APPENDIX

Protocol for a phase 3, randomised, active-control study of four-factor prothrombin complex concentrate versus frozen plasma in bleeding adult cardiac surgery patients requiring coagulation factor replacement: the LEX-211 (FARES-II) trial

Keyvan Karkouti MD, Jeannie Callum MD, Justyna Bartoszko MD, Cristina Solomon MD, Sigurd Knaub PhD, Jerrold H. Levy MD, Kenichi Tanaka MD, on behalf of the FARES-II Study Group

Contents

FARES-II STUDY GROUP

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List of Sites, Investigators, Study Coordinators, and Research Ethics Boards and Approvals:

Toronto General Hospital (University Health Network), Toronto, Ontario**:** Justyna Bartoszko, Keyvan Karkouti, Stuart McCluskey, Deep Grewal, Jo Carrol, Nishanthi Liyanage, Humara Poonawala, Simryn Selby, Reezanoor Kabir, Shelley Oliver, Alioska Escorcia, Susana Medic.
(Board of Records/REB: University Health Network-Research Ethics Board [UHNREB], 700 University Avenue, 4th floor, Toronto, ON M5G 1Z5; ethics approval reference number 3996.)

Royal Columbian Hospital/Fraser Health Authority, New Westminster, British Columbia**:** Sukhpal Brar, Daniel Wong, Michael Law, Michelle Wong, Mathew Yan, Michelle Mozel, Ramanjot Kaur, Rebecca Randall, Kelly Bizovie, Sarah Buchko, Raven Arly Gonzales, Korey Sutherland, Jenna Van Roekel, Alveena Babul.
(Board of Records/REB: Fraser Health Research Ethics Board, Department of Evaluation and Research Services #400, 13450 102nd Avenue, Surrey, BC V3T 0H1; ethics approval reference number 2022362.)

Oklahoma Health Sciences Centre, Oklahoma City, OK**:** Ken Tanaka, Kofi Vandyck, Amir Butt, Penny Johnson, Hisako Okada.
(Board of Records/REB: University of Oklahoma IRB for the Protection of Human Subjects, 865 Research Parkway, Suite 400, Oklahoma City, OK 73104; ethics approval reference number IRB00000729.)

Kingston Health Sciences Centre, Kingston, Ontario**:** Tarit Saha, Deborah DuMerton, Robert Tanzola, Reegan Tod, Bethany Smethurst, Shagun Jain, Aiden Scholey, Angela Sirosky-Yanyk, Andrew Stevens, Jeannie Callum.
(Board of Records/REB: University Health Network-Research Ethics Board [UHNREB], 700 University Avenue, 4th floor, Toronto, ON M5G 1Z5; ethics approval reference number 3996.)

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(Board of Records/REB: NAGANO, Autorisation de Réaliser la Recherché 5000, Rue Bélanger, Montréal [Québec] H1T 1C8; ethics approval reference number MP-10-2023-3879, 22268.)

Vancouver General Hospital (Vancouver Coastal Health): Darren Mullane, Bevan Hughes, Sakara Hutspardol, Andrew Shih, Shirley Lim, Jian Mi, Debbie Kalar and Matthew Eang.
(Board of Records/REB: University of British Columbia Clinical Research Ethics Board, 210-828 West 10th Avenue Vancouver, BC V5Z 1M9; ethics approval reference number H22-00837.)

Duke University Health System, Durham, NC**:** Kamrouz Ghadimi, Erick Lorenzana-Saldivar, Edward P. Chen.
(Board of Records/REB: Duke University Health System Institutional Review Board [DUHS IRB], Suite 900 Erwin Square, 2200 West Main St. Durham, NC, 27705; ethics approval reference number FWA00009025.)

Sunnybrook Health Sciences Centre, Toronto, Ontario**:** Yulia Lin, Fuad Moussa, Akash Gupta, Angela Jerath, Philip Lau, Pablo Perez D'Empaire, Sophia Wong, Chantal Armali, Lilia Kaustov, Amie Malkin, Connie Colavecchia, Harley Meirovich, Jane Yang.
(Board of Records/REB: University Health Network-Research Ethics Board [UHNREB], 700 University Avenue, 4th floor, Toronto, ON M5G 1Z5; ethics approval reference number 3996.)

Institut Universitaire de Québec (Universite Laval), Ville du Québec, Québec**:** Etienne Couture, Annie Bergeron, Francois Laforge, Kim Paradis, Nathalie Gagne, Marie Soleil Saillant, Marie-Claude Vézina, Olivier Royer, Eric Dumont, and Marie-Ève Charest.
(Board of Records/REB: NAGANO, Autorisation de Réaliser la Recherché 5000, Rue Bélanger, Montréal [Québec] H1T 1C8; ethics approval reference number MP-10-2023-3879, 22268.)

University Hospital (London Health Sciences Centre), London, Ontario: Christopher Harle, Raffael Zamper, Mackenzie Quantz, Robert Mayer, Jeff Kinney, Lee-Anne Fochesato, Yuxin Bai.
(Board of Records/REB: University Health Network-Research Ethics Board [UHNREB], 700 University Avenue, 4th floor, Toronto, ON M5G 1Z5; ethics approval reference number 3996.)

McMaster University (Hamilton Health Sciences), Hamilton, Ontario**:** Michelle Zeller, Iqbal Jaffar, Summer Syed, Nour Alhomsi, Janine Guevarra, Erin Jamula, Wan Chien (Betty) Hsu, Abbey Drew.
(Board of Records/REB: University Health Network-Research Ethics Board [UHNREB, 700 University Avenue, 4th floor, Toronto, ON M5G 1Z5; ethics approval reference number 3996.)

Ottawa Heart Research Institute (University of Ottawa), Ottawa, Ontario**:** Diem Tran, Hakan Buyukdere, Fraser Rubens, Drashtee Patel, Melanie Tokessy, Elizabeth Watt, Hadia Arabi Katbi, Kim Luciano.
(Board of Records/REB: University Health Network-Research Ethics Board [UHNREB], 700 University Avenue, 4th floor, Toronto, ON M5G 1Z5; ethics approval reference number 3996.)

St. Michael's Hospital (Unity Health Toronto), Toronto, Ontario: Katerina Pavenski, Amy Moorehead, Gianluigi Bisleri, David Mazer, Kamola Kasimova.
(Board of Records/REB: University Health Network-Research Ethics Board [UHNREB], 700 University Avenue, 4th floor, Toronto, ON M5G 1Z5; ethics approval reference number 3996.)
This site was initiated but has not had the opportunity to contribute any patients.

MODEL INFORMED CONSENT FORMS (ICFs)

- Canadian ICF (template for Ontario province): FARES-II ICF V2.0_19-July-2022_Clean
- United States master ICF: LEX-211_US Master ICF Adult V5.0_18 Mar 2024_final_Clean

Informed Consent Form for Participation in a Research Study

Study Title:	**FARES-II**: FActor REplacement in Surgery-II Study
Study Doctors:	Dr. _____; Department of _____ (Phone:_____) Dr. _____; Department of _____ (Phone:_____) insert name, department and telephone or pager number
Sponsor/Funder:	Octapharma AG, Seidenstrasse 2, CH-8853 Lachen, Switzerland
Co-ordinating Investigators	Dr. Keyvan Karkouti; Department of Anesthesia, Toronto General Hospital, UHN Dr. Jeannie Callum: Transfusion Medicine, Kingston Health Sciences Centre
Grant:	Canadian Institute of Health Research (CIHR)
Emergency Contact Number	_____

INTRODUCTION

The purpose of this document is to inform you that you were enrolled in an approved research study while you were having surgery and to request your consent for continued participation. Please note that the information below relates to the above research study in which you (the patient) or a member of your family was enrolled. In the event, the person reading this notification is the family member/Substitute Decision Maker (SDM) and not the patient, then all references to "you" refer to the patient who was enrolled in the research study. The following provides detailed information relating to the study.

This consent form provides you with information to help you make an informed choice. Please read this document carefully and ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this research study.

Please take your time in making your decision. You may find it helpful to discuss it with your friends and family. Your continued participation in this study is voluntary. You have the right to refuse your continued participation in this study. If you do decide to take part, you can still withdraw from the study at any time without any negative consequences to the medical care, education, or any other services you may be entitled to or are presently receiving.

IS THERE A CONFLICT OF INTEREST?

Describe any conflict of interest that exists or may appear to exist as it relates to any of the investigators, study staff or member of their immediate family. A conflict of interest exists if there is a potential benefit to the investigator(s), study staff or member of their immediate family beyond the professional benefit from academic achievement or presentation of the results. Examples include, but are not limited to, speaker's fees, travel assistance, consultant fees, honoraria, gifts, and intellectual property rights such as patents. A declaration of conflict of interest should include the identity of the person with the conflict of interest, the type of incentive or inducement, and its source. See examples below.

The *insert recipient of funding e.g., hospital* is receiving financial payment from the Sponsor to cover the cost of running this study. The investigators (study doctors) and the organizations funding the study have an interest in completing this study. Their interests should not influence your decision to participate in this study. You should not feel pressured to join this study.

WHAT IS THE BACKGROUND INFORMATION FOR THIS STUDY?

Each participating site must ensure that the standard or usual treatment described in below matches the standard of care at that site. Site specific differences must be reflected in the Centre Initial Application and the site-specific consent form.

The study investigators are conducting a research study to compare how well something works and the safety of two approved therapies that contain clotting factors and are used routinely during or after heart surgery to help stop bleeding caused by reduced clotting factor levels in the blood. When blood vessels are injured during surgery, clotting factors that are circulating in blood are activated at the site of injury, leading to the formation of blood clots that seal the site of injury and stop the blood loss.

In about 1 in 10 cases, patients develop major bleeding during heart surgery because of reduced clotting factor levels. Since major bleeding can lead to serious complications and death, doctors try to rapidly diagnose the cause of bleeding and initiate appropriate treatment. As a result, doctors routinely measure clotting factor levels in bleeding patients, and if the levels are low, they initiate treatments that increase clotting factors levels.

There are currently two therapies that are approved by Health Canada for intravenous (via a needle through the vein) treatment of bleeding related to low clotting factor levels:

- **Plasma,** which is derived from whole blood, frozen while in storage and thawed prior to administration.
- **Prothrombin Complex Concentrate (PCC**), which is stored as a powder and mixed with sterile water before it is administered. The PCC used in this study is called Octaplex and is made by *Octapharma*, the study sponsor.

During your surgery, major bleeding caused by low clotting factor levels occurred, and your doctors ordered one of the two available therapies to treat the condition and stop your bleeding. As a result, you were enrolled into this study.

WHY IS THIS STUDY BEING DONE?

Both of these blood products are standard of care at UHN and each therapy has its own benefits and risks. We do not know if one is better to use than the other for certain bleeding situations during or after heart surgery, so we are doing this study to find out.

WHAT OTHER CHOICES ARE THERE?

Since we cannot predict which patients will bleed due to low clotting factor levels during surgery, and since the treatment needs to be started right away to stop the bleeding, special permission has been given by the ethics board and Health Canada to change the usual consent process. Instead of reviewing the study with you and obtaining your consent before enrolling you in the study, you were automatically enrolled into the study when your doctors ordered either PCC or plasma to stop your bleeding. At that time, you were randomly (by chance) assigned to receive one of the two products being studied.

Depending on your clinical situation, your doctors may have ordered the product simply to have it on-hand in case it was needed (in which case you may not have received either of the products if they decided that it was not needed), or you may have received one or more doses of the products.

There were no changes to any other aspect of your care, and the only decision you need to make now is if you will allow your information to be used in the study. Participation in the study is purely voluntary and you can withdraw from the study at any time.

If you do not want to be contacted by the research team, you can agree for your data to be collected but request that no follow-up call or visit occur at the end of the trial. If you decline to participate in the trial, none of your information will be collected other than which clotting factor you were assigned to receive.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

This study is being conducted at 10-12 hospitals across Canada and the United States and will eventually include at least 500 patients.

This study should take 2 years to complete and the results should be known in about 2.5 years.

WHAT WILL HAPPEN DURING THIS STUDY & WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?

As noted above, you were automatically enrolled into the study when your doctors ordered either PCC or plasma to stop your bleeding, and depending on the clinical situation, you may not have received either of the products, or you may have received one or more doses of the products.

Which therapy you were assigned to was based on random assignment (i.e., like flipping a coin; 50/50 chance). This is a partially blinded study, which means that neither you, the study doctors, nor the study staff know which product you received. Only your health-care providers in the operating room and the blood bank department know which products you received. Your group assignment can be identified if medically necessary. Requests to reveal your assignment for your information or participation in other research studies will not be considered until this study has been completed and the results are known.

No other aspect of your care will be modified. You may be contacted up to 45 days after your surgery in order to obtain your consent.

As part of your routine hospital care, you will have laboratory and radiological tests performed. We will be collecting this information along with reviewing your doctor's notes regarding your surgery and recovery from your medical records for the first 30 days after surgery or until you are discharged from the hospital, whatever occurs first.

After providing consent, there will be only one additional telephone call with the research staff that will occur 30 days after your surgery. Research staff will be contacting you to see how you are doing and to ask if you have required any additional medical treatment after your surgery. If you are still in hospital 30 days after your surgery, this visit will occur in person. This will take no more than 5-10 minutes.

HOW LONG WILL PARTICIPANTS BE IN THE STUDY?

The study intervention will last until the bleeding is under control or for 24 hours after enrollment, whichever occurs first. We will collect data on you for the first 30 days after your surgery and may contact you up until 45 days after your surgery.

CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?

If you have any concerns, please do not hesitate to discuss them with us. Withdrawal from the study is possible at any time, which will not have any impact on the quality of your care. The study information collected prior to your withdrawal will still be used to help answer the research question. Please let your study doctor know.

CAN PARTICIPATION IN THIS STUDY END EARLY?

The study doctor may stop your participation in the study early, if:

- The study intervention does not work for you and your OR doctors no longer feel this is the best option for you
- You are unable to tolerate the study intervention
- The Sponsor decides to stop the study
- A Regulatory Agency or the research ethics board withdraws permission for this study to continue

If you are removed early from this study, the study team will still ask permission to collect data from your chart and continue to follow you for the 30-day duration of the study.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

As you have already received the products to stop bleeding during or after surgery, you face no additional risks.

Both products have known side effects that are listed below, and hospital staff routinely monitor patients who receive these products for any possible side effects.

The two products being compared in this study are thought to be similar in terms of risks. The risks from both products include:

1. Allergic or hypersensitivity reaction. This can include redness of skin, hives, wheezing, tightness of chest and low blood pressure. In rare cases it can lead to anaphylaxis (a severe allergic reaction) or shock (<5%). This is a rare complication and symptoms start during or very soon after administration of the products.
2. Transfusion-related acute lung injury. This is a rare complication (<1 in 10,000) that can lead to respiratory distress. This complication starts soon after administration of the products and can develop within the next 6 hours.
3. Transfusion-associated circulatory overload. This is a reaction that can occur due to a rapid transfusion of a large volume of coagulation factor products (<5%). This side effect can develop within 6 hours of administration.
4. Thromboembolic event. This is the formation of a clot in a blood vessel that breaks loose and is carried by the blood stream to plug another vessel. The clot may plug a vessel in the lungs (pulmonary embolism), brain (stroke), gastrointestinal tract, kidneys or leg. It is unknown if either product increases the risk of this complication (<5%). This can occur any time after your surgery and may or may not be related to the products. If this complication occurs, your study doctor will carefully review your records to determine if it was related to the products.
5. Infection from coagulation factor products. Whenever medical products are derived from human blood or plasma, there is a possibility of transmitting infective agents, including viruses and bacteria. The blood supplier, the hospital and pharmaceutical companies have a very strict protocol they follow to prevent this from happening (<1 in 1 million). This can occur any time after your surgery and will monitored by hospital staff.

There is also a possibility of risks that we do not know about and which have not been recorded in medical books or seen in study participants to date. You will be very closely monitored during your time at the hospital and any complications will be quickly identified and managed.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

You will not receive any direct benefit from being in this study. However, information learned from this study will help to guide future treatment options in other patients.

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

Note: If there will be disclosure of personal identifiers, i.e., disclosed on any research-related information/documents including samples or scans, or as part of the unique identifier, these disclosures must be justified in the REB application and approved. Please ensure that you are aware of institutional and REB policies with respect to the disclosure of personal identifiers.

Protecting and keeping your medical information confidential is very important to us. We will remove all personal identifying information such as name, address, date of birth etc. from all documents and information collected and you will be given a unique study number.

The study doctor and his/her study team will look at your personal health information and collect only the information they need for the study.

Personal health information (PHI) is any information that could identify you and includes your:

- name,
- date of birth,
- Phone number, email
- New or existing medical records, which includes types, dates and results of medical tests or procedures.

The study doctor will keep any personal health information about you in a secure and confidential location for a minimum of 15 years as required by Health Canada. A list linking your study number with your name will be kept by the study doctor in a secure place, separate from your study file.

Representatives of Clinical Trials Ontario, a not-for-profit organization, may see study data that is sent to the research ethics board of record for this study. Your name, address, email, or other information that may directly identify you will not be used.

In case any adverse events are believed to be related to this research study, PHI will be removed, and the appropriate data will also be sent to relevant regulatory agencies: Canadian Blood Services (supplier of the plasma) and Octapharma (supplier of PCC) for the purpose of product safety.

The study team or the people/groups listed below will be allowed to look at your records.
The following people or organizations may come to the hospital to look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study is following proper laws and guidelines:

- Representatives of the research ethics board of record or the ethics committee, who oversee the ethical conduct of research studies at the hospital
- Octapharma, the Sponsor of this study
- Ozmosis Research Inc., the Clinical Research Organization helping mange this study
- Government regulatory authorities (i.e. FDA or Health Canada)
- This institution and affiliated sites who oversee the conduct of research at this location

Study Information that Does Not Identify You

Information about you will have a code and will not show your name or address, or any information that directly identifies you. All information collected during this study, including your PHI, will be kept confidential and will not be shared with anyone outside the study unless required by law. You will not be

named in any reports, publications, or presentations that may come from this study.

After all your personal identifiers have been removed, the research related data collected will be stored on a secured web-server at ERGOMED, which is a global company specializing on the conduct of clinical trials (headquartered in England; secured database centre located in Germany). This method of data storage meets all Canadian privacy laws.

In addition, the study data will also be stored on an Octapharma-secured server to look for healthcare trends and to help researchers better understand common trends between your condition and other health problems.

Studies involving humans sometimes collect information on race and ethnicity as well as other characteristics of individuals because these characteristics may influence how people respond to different interventions. Providing information on your race or ethnic origin is voluntary.

If you prefer, we may communicate via email to forward the informed consent form for you to read and sign, especially in instances when you have left the hospital before signing the consent form or if your SDM does not live close by. Communication via e-mail is not absolutely secure. We do not recommend that you communicate sensitive personal information via e-mail.

If the results of this study are published, your identity will remain confidential. It is expected that the information collected during this study will be used in analyses and will be published/presented to the scientific community at meetings and in journals. This information may also be used as part of a submission to regulatory authorities around the world to support the approval of the study intervention.

Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

A copy of the consent form that you sign to enter the study will be included in your health record/hospital chart.

WILL FAMILY DOCTORS/HEALTH CARE PROVIDERS KNOW WHO IS PARTICIPATING IN THIS STUDY?
Your family doctor/health care provider will not be informed that you are taking part in the study. You can choose to let your family doctor/health care provider know, if you like.

WILL INFORMATION ABOUT THIS STUDY BE AVAILABLE ONLINE?
A description of this clinical trial will be available on http://www.clinicaltrials.gov. This website will not include information that can identify you. The site will include a summary of the study and eventually the results. You can search this site at any time.

WHAT IS THE COST TO PARTICIPANTS?
Participation in this study will not involve any additional costs to you or your private health care insurance.

ARE STUDY PARTICIPANTS PAID TO BE IN THIS STUDY?
You will receive no payment or incur any study related costs upon agreeing to remain in this study.

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

If you were harmed as a direct result of taking part in this study, all necessary medical treatment will be made available to you at no cost.

By signing this form you do not give up any of your legal rights against the investigators, sponsor or involved institutions for compensation, nor does this form relieve the investigators, sponsor or involved institutions of their legal and professional responsibilities.

You have the right to receive all information that could help you make a decision about participating in this study. You also have the right to ask questions about this study and your rights as a research participant, and to have them answered to your satisfaction, before you make any decision. You also have the right to ask questions and to receive answers throughout this study.

You will be given a copy of this signed and dated consent form.

WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

If you have questions about taking part in this study, or if you suffer a research-related injury, you can talk to your study doctor, or the doctor who is in charge of the study at this institution. That person is:

_____	_____
Name	Telephone

If you have questions about your rights as a participant or about ethical issues related to this study, you can talk to someone who is not involved in the study at all. That person is:

University Health Network-Research Ethics Board	(416) 581-7849
Name	Telephone

SIGNATURES
Study Title: **FARES-II**: FActor REplacement in Surgery-II Study

Name of Participant: _____

Participant/Substitute Decision-Maker
By signing this form, I confirm that:

- All of my questions have been answered,
- I understand the information within this informed consent form,
- I allow access to medical records and related personal health information as explained in this consent form,
- I do not give up any legal rights by signing this consent form,
- I agree, or agree to allow the person I am responsible for, to take part in this study.

Signature Of Participant/SDM	Printed Name	Date	Relation to Participant

Signature Of Person Conducting The Consent Discussion	Printed Name & Role	Date

The following attestation must be provided if the participant is unable to read or requires an oral translation:
If the participant is assisted during the consent process, please check the relevant box and complete the signature space below:

☐ The person signing below acted as an interpreter, and attests that the study as set out in the consent form was accurately sight translated and/or interpreted, and that interpretation was provided on questions, responses and additional discussion arising from this process.

PRINT NAME of Interpreter	Signature	Date	Language

☐ The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to the participant, and any questions have been answered.

PRINT NAME of Witness	Signature	Date	Relation to Participant

Please note: More information regarding the assistance provided during the consent process should be noted in the medical record for the participant if applicable, noting the role or relationship of the impartial witness.

PATIENT INFORMATION SHEET AND INFORMED CONSENT FORM

for

FActor REplacement in Surgery

Four-Factor Prothrombin Complex Concentrate versus Frozen Plasma in Bleeding Adult Cardiac Surgical Patients ("FARES-II" Study)

(LEX-211)

Dear Patient,

Before a drug can be put on the market, scientific research involving patients' needs to be carried out. Such research is called a "clinical trial" or "clinical study" and is subject to strict rules and close medical surveillance. You are invited to take part in such a research study. The study is conducted by Octapharma AG, Seidenstrasse 2, CH-8853 Lachen, Switzerland (sponsor). Approval for the study has been given by the research ethics board. It will be conducted in accordance with the applicable regulatory requirements.

Your study doctor will explain to you all relevant aspects of the study. In addition, please take time to read the following information carefully. Ask if there is anything that is not clear or if you would like more information. If you decide to take part, please sign the enclosed informed consent form.

Purpose of the study

The study investigators are conducting a research study to compare two therapies that contain coagulation factors and that can be used to stop major bleeding during or after heart surgery. Major bleeding is an unexpected complication of heart surgery that occurs in about 1 in 10 operations. Major bleeding can lead to serious complications and death if it is not rapidly and optimally treated.

While there are several causes of bleeding during surgery, one important cause is a drop in clotting factors to levels below what are needed to form functioning blood clots to stop bleeding. For this reason, your doctors routinely measure clotting function when unexpected bleeding happens, order clotting factor supplements when the levels are too low and transfuse the clotting factors to stop the bleeding.

For treatment of bleeding that occurs during heart surgery, fresh frozen plasma is the standard of care in the US. Plasma contains coagulation factors, and it is usually given after fibrinogen and platelets have been replaced. The purpose of this study is to find out if prothrombin complex concentrate (PCC) is as effective as plasma for treating bleeding during heart surgery. The safety of the two products will also be compared. Both PCC and plasma are derived from donated blood. Plasma is obtained from whole blood, frozen while in storage, and thawed before being transfused into a patient. PCC contains purified coagulation factors which are treated to inactivate viruses. PCC is stored as a powder and mixed with water before being transfused into a patient. Both products have been approved in many countries worldwide, including Canada and the USA. However, PCC was approved in the USA in July for the treatment of a

different type of bleeding. It is not approved in the USA for the treatment of bleeding patients undergoing heart surgery and therefore is still considered an investigational product. In most countries where the PCC is approved, it is known under the name of *Octaplex*. In the USA, it is approved under the tradename *Balfaxar.*

Both plasma and PCC have been shown to help stop bleeding during and after heart surgery. In a previous pilot study (the FARES study), patients who were treated with PCC had significantly less blood loss and needed fewer blood product transfusions compared with patients who were treated with plasma. Therefore, the pilot study demonstrated how PCC use may directly benefit patients, as both bleeding and transfusions during heart surgery have been associated with increased morbidity and mortality. The FARES study also looked at safety in patients treated with PCC or plasma and found that the risks associated with treatment were similar between the two products.

Several other clinical studies have shown that the efficacy and safety of PCC are generally comparable to plasma in patients undergoing heart surgery. However, PCCs have been shown to be associated with a lower risk of adverse events such as transfusion-related acute lung injury and a transfusion-related circulatory overload compared with plasma. PCCs also have a lower risk of infection than plasma. PCCs can be administered quickly as they do not need to be thawed before use. The volume of a dose of PCC is much smaller than that of a dose of plasma, which means that it takes less time to give patients PCC than plasma.

The decision to treat you with one of the two study supplements for this study will be based on objective clinical and laboratory criteria and will only be made after your test results indicate that such treatment is needed.

Your participation in this study is completely voluntary. You may decide not to be in this study, or to be in the study now, and then change your mind later. You may leave the study at any time without affecting your care.

Funding for this study is being provided by Octapharma, which makes the PCC that is used in the study.

This study is being conducted at 10 hospitals in Canada and 2 in the United States. It will eventually include 500 patients and take two years to complete. Your participation in this study will last for 30 days.

Study procedures

Main criteria for participation

For participation in this study, you must be 18 years or older and undergoing any heart surgery that uses cardiopulmonary bypass. Before you are enrolled in the study, your study doctor will first check that you fit all of the other study inclusion and exclusion criteria and that you are therefore eligible to take part. You will only receive PCC or plasma if your doctors order it for you during the operation, either to manage bleeding or because they anticipate bleeding due to the type of surgery that you are undergoing. Your doctors will also have to know, or suspect, that you have a clotting factor deficiency.

Procedures

As part of your routine hospital care, you will have laboratory and radiological tests performed.

You will not undergo any additional testing as part of this study. We will be collecting this information from your medical chart along with your general well-being during the follow-up period. This will entail follow-up visits by the research team to your bedside while you are in the hospital. Your final visit will be on day 30 after treatment and will be carried out in person if you are still in the hospital, or by telephone if you are discharged earlier.

Treatment and examinations at visits

If you experience excessive bleeding during surgery, your doctors may decide that you need clotting factor supplementation (plasma or PCC) to stop your bleeding. The decision to treat you with plasma or PCC will be based on objective clinical and laboratory criteria and will only be made after your test results indicate that such treatment is needed. If so, your doctors will record your weight and confirm that you are eligible for the study before ordering the treatment. The dose for *Octaplex* will be 1500 IU if you weigh ≤60 kg and 2000 IU if you weigh >60 kg. The dose for plasma will be 3 U if you weigh ≤60 kg and 4 U if you weigh >60 kg. The therapy you receive will be based on random assignment (i.e., like flipping a coin; 50/50 chance). Your doctors in the operating room will know which product you receive. Your doctors may also decide that you need a second dose of clotting factor supplementation within 24 hours after your first treatment, in which case you will receive the same product as before. Once the maximum dose of PCC is administered, if additional doses of coagulation factors are needed all patients will receive plasma.

The following assessments will only be recorded if you received PCC or plasma during your operation, as part of the study. If you did not receive PCC or plasma as part of the study then monitoring will continue for 30 days for side effects and routine assessments will be performed as part of your normal care.

You will be closely monitored for 24 hours after receiving PCC or plasma. If not already recorded, your doctors will collect information on your sex, age, height, body mass index, medical history, and any medications you have been taking. Your doctors will also administer additional doses of coagulation factor supplementation as needed and carry out any laboratory tests that are part of your routine care. As part of the study, your doctors will collect information about your surgery, such as how many transfusions you received, how much blood loss you experienced, and whether you experienced any symptoms or side effects. Monitoring will continue for up to 7 days, depending on when you are discharged from the hospital. This monitoring includes any assessments that are part of your routine care.

Final examination

After 30 days, a final examination will be performed. This will be conducted in person if you are in the hospital, or by telephone in case you are already discharged. Your doctors will ask you for information about what medications you are taking and whether you are experiencing any symptoms or side effects.

Other therapies

You are allowed to take other therapies that are part of your standard care. Your doctor will record the therapies you have taken, both before surgery and throughout the study.

Subject responsibilities

It is absolutely essential that you inform the study doctor before study start about all previous diseases and medications you are taking, about allergies and any special intolerances. It is equally important that you inform the doctor about any impairment of your health or well-being during the study even if you consider a relationship to the treatment as unlikely.

The successful conduct of this clinical study depends on the co-operation of the study participants. Therefore, we ask that you strictly adhere to the scheduled appointments and times, as well as to the instructions of your study doctor.

Undesirable effects and risks for the patient

Apart from the desired effect, any therapeutic substance may have undesirable/adverse effects.

The two products being compared in this study are thought to be similar in terms of risks. The risks from both products include:

1. Allergic or hypersensitivity reaction. This can include redness of skin, hives, wheezing, tightness of chest and low blood pressure. In rare cases it can lead to anaphylaxis (a severe allergic reaction) or shock (<5%).
2. Transfusion-related acute lung injury. This is a rare syndrome that causes sudden respiratory distress within 6 hours of a transfusion (<1 in 10,000)
3. Transfusion-related circulatory overload. This is a transfusion reaction that can occur due to a rapid transfusion of a large volume of coagulation factor products (<5%).
4. Thromboembolic event. This is the formation of a clot in a blood vessel that breaks loose and is carried by the blood stream to plug another vessel. The clot may plug a vessel in the lungs (pulmonary embolism), brain (stroke), gastrointestinal tract, kidneys, or leg. It is unknown if either product increases the risk of this complication. Blood clots causing events including stroke have been reported in patients receiving PCC or plasma. In the current LEX-211 study, 5.5% of patients receiving PCC or plasma have had a thromboembolic event. In a previous study with PCC vs. plasma (the FARES study), 7.4% of the patients in the PCC group and 8.2% of the patients in the plasma group had a thromboembolic event. In a large study with similar patients in cardiac surgery (the FIBRES study), 8.3% of the patients had a thromboembolic event.
5. Infection from coagulation factor products. Whenever medical products are derived from human blood or plasma, there is a possibility of transmitting infective agents, including viruses and bacteria. The blood supplier, the hospital and pharmaceutical companies have a very strict protocol they follow to prevent this from happening (<1 in 1 million).

There is also a possibility of risks that we do not know about and which have not been recorded in the medical literature or seen in study participants to date. You will be very closely monitored during your time at the hospital and any complications will be quickly identified and managed.

Benefits of taking part in the study and alternative treatments

Although all patients who participate in this trial will have the potential to benefit, we cannot guarantee that there will be any benefit to you. So far, PCC has shown a very favorable safety profile. PCC is treated and filtered to reduce the risk of infection, it can be administered quickly

and in predictable doses, and has substantially lower risk of transfusion-related acute lung injury and transfusion-related circulatory overload compared with plasma, making PCC likely to be safer than plasma and at least as effective as plasma in stopping unexpected bleeding. As PCC does not contain the full complement of clotting factors that plasma contains, it is possible that PCC may not be as effective as plasma. However, if PCC does not control bleeding after a patient receives two doses, plasma will be administered. Information learned from this study will help to guide future treatment options in other patients.

As a participant in this study, you will be under careful medical surveillance to ensure your safety.

While FP and PCC are treatment options for patients with bleeding due to a deficit in coagulation factors leading to a prolongation of clotting times, bleeding in cardiac surgery may have also other causes, such as fibrinogen deficit, or a deficit in platelet count or function. Please feel free to discuss the alternatives with your study doctor, who can provide you detailed information about the potential benefits and risks of the various treatment options available to you.

Insurance cover

As a participant in the study, you are insured in accordance with applicable laws to cover any occurrence of health damage associated with your participation in the study. This does not apply to a deterioration of your health or the worsening of existing diseases that would have occurred without you being a study participant. In the unlikely event that you experience a study-related injury, medical care to the extent needed and available will be provided.

Insurance has been taken out with XXX (name, address, telephone number and policy number XXX) with a total insurance sum of XXX USD. You will receive copies of the insurance conditions. Please pay attention to § X and § X referring to insurance benefits and obligations.

In order not to jeopardize the insurance cover, any treatment by other doctors may be provided only in agreement with the study doctor - except for emergency cases.

In case of an injury please inform your study doctor (see "contact information" on page XX) immediately. Your doctor will then inform the insurance company in your name and provide you with a copy of the notification.

Compensation

You will not receive monetary compensation for your participation in this study. The sponsor will pay the costs for this clinical study. No costs will be incurred by you if you participate in this study. Any travel expenses resulting from your participation (e.g., for follow-up visits) will be reimbursed.

Data protection

During this clinical study, your personal data and medical findings will be collected.

Any and all personal data provided within the context of this trial are available exclusively to the trial physicians, their deputies and authorized persons (such as representatives of the sponsor of the trial or of the appropriate regulatory agencies), who are all bound to confidentiality.

Personal data will not be published (including publication of the trial results such as in a scientific publication). Data passed on to third parties will be pseudonymised. This means that your name will be assigned a number, and the information we collected about you will only be passed on using that number. The list providing the assignment of this number to your name remains with the investigator.

Your personal data will be stored and reviewed according to the law. Third parties who will receive your pseudonymized data include competent authorities like Health Canada and the U.S. Food and Drug Administration, the sponsor or its representatives, the relevant ethics committees and, if applicable, any third party for the purpose of scientific evaluation.

If you choose to be in this study, your study doctor (investigator) will gather and use your personal data to conduct the study. The personal data may include:

- Your name, address and contact details
- Year of birth
- Demographic information, such as race, ethnicity, and gender
- Medical history, including past and present medical records
- Information from your study visits, including test results, diary entries, images, genetic and tissue samples

Your personal data will be collected and recorded by the study doctor in your personal medical record and stored using a computer. Your personal data collected will be pseudonymized by the study doctor. The process of pseudonymization of your information means that your personal identifiers (such as name, date of birth, and address) will be replaced by a number. The study doctor will create and archive an identification list, with which your pseudonymized information can be traced back to you personally, to the extent permitted and necessary. This information will be protected against unauthorized access. Re-identification will take place only under the conditions prescribed by law.

For a proper conduct of the study, it is necessary that authorized representatives of the sponsor (monitor, auditor), members of the ethics committees/IRBs as well as regulatory authority inspectors from here and abroad (including the US Food and Drug Administration) look at your personal medical records by direct access. These persons are obliged to keep your data strictly confidential.

Any information about your personal data that leaves this hospital will be pseudonymized, apart from any that will be sent to your general practitioner (family doctor), so that you cannot be recognized from it.

The sponsor and those working for them may use your pseudonymized personal data sent to them only in compliance with data protection regulations:

- To see if the study drug works
- To see if the study drug is safe
- For other research activities related to the study drug
- To ensure that applicable laws and procedures are being followed by the study

- To make any reports required by applicable laws

The sponsor will provide your pseudonymized personal data to regulatory authorities including the US Food and Drug Administration for the purpose of obtaining marketing authorization.

Your pseudonymized personal data may also be transferred to other countries for processing, including those that do not have data protection legislation as strong as in your country such as for example the United States of America. It will be ensured that all transfers are made in accordance with applicable laws and that your pseudonymized personal data will be secured with adequate technical and organizational measures at all times.

In the future, Octapharma may continue to use your health information that is collected as part of this study. For example, Octapharma may combine information from this study with the results of other studies to re-analyze the safety and efficacy of the study medication, to evaluate other products or therapies, to develop a better understanding of a disease, or to improve the design of future research studies. Octapharma may also share information from the study with regulatory agencies in foreign countries.

A description of this clinical study will be available on http://www.ClinicalTrials.gov, as required by US Law, and potentially on other public websites as required by international legislation. These websites will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

If you decide to withdraw from study participation, the data that has already been collected up to the point of withdrawal of your consent, may still be used.

The Federal Health Insurance Portability and Accountability Act (HIPAA)

The study doctor shall ensure that each patient is able and willing to and has executed an authorization form which meets the requirements of the Health Insurance Portability and Accountability Act (“HIPAA”), and applicable implementing regulations, which include the Standards for Privacy of Individually Identifiable Health Information.

The patient authorization must allow Octapharma to receive and review the patient’s protected health information, which may be re-disclosed to any authorized representative of Octapharma or central laboratory facility for review of patient medical records in the context of this study.

Personal Rights and their Exercise

You are entitled to the rights listed below unless these rights are overruled by other laws/regulations or unless other legal regulations or predominant legitimate interests prevail. To assist you in exercising these rights, please contact the study doctor.

Please be aware that your rights to access, change, move or delete your personal data are limited, as your information have to be managed in a specific way in order for the study to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. In any case, to safeguard your rights, we will use the minimum personally-identifiable information possible.

You have the right to receive information concerning your personal data in a structured and standardized format. If the data concerning you is incorrect, you can have it corrected. In

addition, under certain conditions you have the right to restrict the extent to which your data is used.

When the study is over, you may ask to see your personal data. The reason for this restriction is that it is in the public interest of the sponsor, who acts as the controller of the personal data, to maintain the blinded nature of the study and thereby ensure the validity of the study results.

In addition, you may at any time request the deletion of your personal data concerning you, unless its storage is required by other legal regulations or predominant legitimate interests, for example the accuracy and reliability of the study. This will not have any effect on your medical treatment.

Your personal data will be retained for a period determined by applicable laws and regulatory requirements, which could be for the entire life of the study drug or a longer period.

If you have any questions about your rights and how to exercise them, please do not hesitate to contact your doctor (see contact details below).

Voluntary participation

Participation in this clinical study is voluntary. You may withdraw your consent to participating in the study at any time and for any reason without any effect on the quality of care offered and given to you and on the relationship with your Investigator. For safety reasons and in your own interest a final examination should take place if you decide to withdraw.

If you decide to withdraw from the study at any stage, no further personal data will be collected or added to the study database, apart from any follow-up safety information that the sponsor and your research doctor believe to be in your best medical interests. If you do not wish any further personal data to be recorded, it is your responsibility to tell your research doctor.

If you decide to withdraw from the study at any stage, you may choose to request no further analysis to be done on any samples that may have already been collected for this study. It is your responsibility to let the research doctor know if you wish this to happen, otherwise all samples will be used as originally intended.

The Investigator is entitled to withdraw you from the study at any time if your safety or the due performance of the study makes it necessary or if there are other reasons for the discontinuation of the study.

The Institutional Review Board / Independent Ethics Committee which has the responsibility of assessing applications to undertake clinical research has examined this study and has raised no objections from the point of view of medical ethics.

Who can I call if I have questions or in case of an emergency?

We hope to have explained to you all relevant aspects of this clinical study.

For further questions in connection with this study, your doctor and his staff can be contacted:

Study doctor	
Name:	
Address:	
Phone:	
Email:	

In case of questions concerning your rights as a patient and participant in this study and any inquiries, please contact your doctor. If needed he will forward your request to the CRO/sponsor in a pseudonymized form. If you wish, you will be informed about the results of the study as soon as they are available.

If you have questions regarding your rights as a “study subject”, you may contact the responsible local Ethics Committee:

Independent Ethics Committee or Institutional Review Board	
Name:	
Address:	
Phone:	
Fax:	
Email:	

We would like to thank you for reading this information sheet. If you decide to take part in this study, please enter your name on the attached informed consent form, and sign and date it.

INFORMED CONSENT FORM

FActor REplacement in Surgery

Four-Factor Prothrombin Complex Concentrate versus Frozen Plasma in Bleeding Adult Cardiac Surgical Patients ("FARES-II" Study)

(LEX-211)

Patient initials: |__|__|__| Patient number: |__|__|__|__|__|__|__|

Hospital:	
Investigator´s Name:	
Address:	
Phone:	
Email:	

<Name of investigator>…… has informed me in detail about the scope and objectives of this clinical study, about the study medication and possible risks as well as the existing insurance cover and my obligations arising from it.

I have read the patient information sheet and have had the opportunity to ask questions and I have had sufficient time to decide whether to participate. I feel well informed, but I know that I may ask the study doctor for further information at any time.

I will answer all questions to the best of my knowledge and will follow my study doctor's instructions. I understand that my participation in this clinical study is voluntary and that I am free to withdraw at any time, without giving any reason and without my future medical care being affected. I understand that if I withdraw, I cannot be included in the study and I can no longer participate. I also understand that my study doctor may withdraw me from the study if required.

If I am hospitalized or receive treatment at a health care facility other than the study center during the course of this study, I agree to allow the investigator access to medical records concerning the treatment received and hospital discharge documents.

I agree to my general practitioner (family doctor) being informed of my participation in the clinical study.

Based on the information available to me I agree to take part in the above study.
I will keep a copy of this patient information sheet and informed consent form including the information about the available insurance for this study.

Participant´s Name:	
Participant´s Signature:	
Date and Time of Signature:	

I have informed the patient in accordance with applicable law.

Name of the Investigator:	
Investigator´s Signature:	
Date and Time of Signature:	

BLANK ELECTRONIC CASE REPORT FORM (eCRF)

- CRF for electronic data capture (EDC): LEX-211_Blank_eCRFs_25Jan2023

octapharma

Merative Clinical Development Blank CRFs

Study Name	LEX-211
Description	Four-Factor Prothrombin Complex Concentrate versus Frozen Plasma in Bleeding Adult Cardiac Surgical Patients ("FARES-II" Study)
Protocol	LEX-211
Alias	FARES-II
Generated	25-JAN-23 20:10:30 GMT

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Revision 2

Schedule

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		Eligibility	10,30	Added by visit schedule rule(s) #96
visit-20	Visit 1		20	Added: by visit schedule rule(s) #97
		Body Weight	20,50	
		Informed Consent	20,70	Added by visit schedule rule(s) #121
		Eligibility	20,20	Added by visit schedule rule(s) #122
		Randomization	20,40	Added by visit schedule rule(s) #100
		IMP Preparation - First Dose	20,60	Added by visit schedule rule(s) #111
		IMP Preparation - Second Dose	20,80	Added by visit schedule rule(s) #112
		Clinical Chemistry - Baseline	20,90	Added by visit schedule rule(s) #104
		Haematology (CBC) - Baseline	20,100	Added by visit schedule rule(s) #105
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visit-30	Visit 2 (POD 0)		30	Added: by visit schedule rule(s) #107
		Demographics	30,30	
		Co-morbidities	30,180	
		Medical History	30,40	Repeats, Maximum= Unlimited Added by visit schedule rule(s) #130
		Pre-Operative Anti-Coagulation Medication	30,50	Repeats, Maximum= Unlimited
		Initial Surgery	30,60	
		IMP Administration - First Dose	30,20	
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		Other Transfusions	30,230	Repeats, Maximum= Unlimited

Unique Identifier	Visit	Visit - Page	Visit ID, Page ID	Notes
		Total Chest Tube Blood Loss	30,130	
		Haemorrhages	30,150	Repeats, Maximum= Unlimited
		Clinical Chemistry	30,70	
		Haematology (CBC)	30,80	
		Coagulation Measures - Coag.	30,90	
		Coagulation Measures - ROTEM	30,210	
		Coagulation Measures - Platelets	30,220	
visit-140	Visit 2 (POD 1)		140	Added: by visit schedule rule(s) #120
		Clinical Chemistry	140,10	
		Haematology (CBC)	140,20	
		Coagulation Measures - Coag.	140,30	
		Coagulation Measures - ROTEM	140,110	
		Coagulation Measures - Platelets	140,120	
visit-50	Visit 3 (POD 2)		50	Added: by visit schedule rule(s) #108
		Clinical Chemistry	50,10	
		Haematology (CBC)	50,20	
		Coagulation Measures - Coag.	50,30	
		Coagulation Measures - ROTEM	50,110	
		Coagulation Measures - Platelets	50,120	
visit-80	Visit 3 (POD 3)		80	Added: by visit schedule rule(s) #113
		Clinical Chemistry	80,10	
		Haematology (CBC)	80,20	
		Coagulation Measures - Coag.	80,30	
		Coagulation Measures - ROTEM	80,40	
		Coagulation Measures - Platelets	80,50	
visit-90	Visit 3 (POD 4)		90	Added: by visit schedule rule(s) #114
		Clinical Chemistry	90,10	
		Haematology (CBC)	90,20	
		Coagulation Measures - Coag.	90,30	
		Coagulation Measures - ROTEM	90,40	
		Coagulation Measures - Platelets	90,50	

Unique Identifier	Visit	Visit - Page	Visit ID, Page ID	Notes
visit-100	Visit 3 (POD 5)		100	Added: by visit schedule rule(s) #115
		Clinical Chemistry	100,10	
		Haematology (CBC)	100,20	
		Coagulation Measures - Coag.	100,30	
		Coagulation Measures - ROTEM	100,40	
		Coagulation Measures - Platelets	100,50	
visit-110	Visit 3 (POD 6)		110	Added: by visit schedule rule(s) #116
		Clinical Chemistry	110,10	
		Haematology (CBC)	110,20	
		Coagulation Measures - Coag.	110,30	
		Coagulation Measures - ROTEM	110,40	
		Coagulation Measures - Platelets	110,50	
visit-120	Visit 3 (POD 7)		120	Added: by visit schedule rule(s) #117
		Clinical Chemistry	120,10	
		Haematology (CBC)	120,20	
		Coagulation Measures - Coag.	120,30	
		Coagulation Measures - ROTEM	120,40	
		Coagulation Measures - Platelets	120,50	
visit-60	Visit 4		60	Added: by visit schedule rule(s) #109
		Additional Surgery	60,10	Repeats, Maximum= Unlimited
		Hospital Admission - Initial	60,50	
		Hospital Re-admissions	60,20	Repeats, Maximum= Unlimited
		Patient Survival	60,30	
		Patient Mortality	60,40	Added by visit schedule rule(s) #141
visit-70	Events		70	Added: by visit schedule rule(s) #101
		Adverse Events	70,10	Repeats, Maximum= Unlimited
		Concomitant Medications	70,20	Repeats, Maximum= Unlimited
visit-130	Additional Assessments		130	Added: by visit schedule rule(s) #118
		Clinical Chemistry	130,10	Repeats, Maximum= Unlimited

Unique Identifier	Visit	Visit - Page	Visit ID, Page ID	Notes
		Haematology (CBC)	130,20	Repeats, Maximum= Unlimited
		Coagulation Measures - Coag.	130,30	Repeats, Maximum= Unlimited
		Coagulation Measures - ROTEM	130,40	Repeats, Maximum= Unlimited
		Coagulation Measures - Platelets	130,50	Repeats, Maximum= Unlimited

Screening

Welcome

[Revision: Revision 2]

(Visit ID = 10 / Visit Display Name = Screening / Visit Abbrev = SCR / PageID = 10 / Page Display Name = Welcome / Description = Welcome Page)

* Welcome to the LEX-211 study, please confirm the country that the patient is undergoing surgery in	○ Canada ○ United States

Once this page is saved please navigate to Visit 1 to complete the 'Body Weight' page, this will then trigger the Informed Consent and Eligibility pages for Canadian patients.

Informed Consent

[Revision: Revision 2]

(Visit ID = 10 / Visit Display Name = Screening / Visit Abbrev = SCR / PageID = 20 / Page Display Name = Informed Consent / Description = Informed Consent)

Please note that although this page appears within this visit this does not mean that this page must necessarily be completed during this visit. If informed consent has not yet been sought, please return to this page at a later date.

* Has the subject/SDM given informed consent?	○ Yes ○ No	
* Date informed consent was signed		(DD-MMM-YYYY)
* Time informed consent was signed		(HH24:MI)
* Protocol version consented to	○ 5.0 (US) - 12-Apr-2022 ○ 6.0 (Canada) - 12-Apr-2022	
* If no, did the subject/SDM:	○ Refuse ○ Not respond/Uncontactable ○ Patient expired before being approached ○ Other	
* Please specify the reason subject/SDM did not give informed consent		
* If no, has the REB given special permission to collect data for this subject?	○ Yes ○ No	
* Which data has the REB given permission to collect?	○ SAEs and hemostatic therapies ○ All Data	

Eligibility

[Revision: Revision 2]

(Visit ID = 10 / Visit Display Name = Screening / Visit Abbrev = SCR / PageID = 30 / Page Display Name = Eligibility / Description = Eligibility Criteria)

Note: Exclusion Criterion #3 in particular should be rechecked on the day of surgery

* Does the patient meet all of the inclusion criteria?
- ○ Yes
- ○ No

Multiple criteria can be selected by holding 'Ctrl' and clicking options below

* If No, indicate all criteria not met
- ☐ INC01
- ☐ INC02
- ☐ INC03
- ☐ INC04

* Does the patient meet any of the exclusion criteria?
- ○ Yes
- ○ No

Multiple criteria can be selected by holding 'Ctrl' and clicking options below

* If No, indicate all criteria met
- ☐ EXC01
- ☐ EXC02
- ☐ EXC03
- ☐ EXC04
- ☐ EXC05
- ☐ EXC06
- ☐ EXC07
- ☐ EXC08
- ☐ EXC09
- ☐ EXC10
- ☐ EXC11

Since the patient did not meet certain inclusion criteria and/or did meet certain exclusion criteria the patient is not eligible to enroll on this study. The below options are therefore not available, please save this page as is and then the patient will be recorded as a Screen Failure.

Based upon a review of the inclusion and exclusion criteria at this visit, the patient is eligible to continue on this study?	○ Yes ○ No
* If No, please specify reason	

Inclusion Criteria

INC01 - Adult (≥18 years old) patients undergoing any index cardiac surgery employing CPB

INC02 - Coagulation factor replacement with PCC or FP ordered in the operating room for: a.Management of bleeding, or b. Anticipated bleeding in a patient who has been on-pump for >2 hours or has undergone a complex procedure (e.g., aortocoronary bypass [ACB] plus aortic valve replacement)

INC03 - Coagulation factor deficiency, either known to exist (e.g., as indicated by elevated EXTEM clotting time [CT] or INR) or suspected based on the clinical situation

INC04 - Patients who have given written informed consent

Exclusion Criteria

EXC01 - Undergoing heart transplantation, insertion or removal of ventricular assist devices (not including intra-aortic balloon pump [IABP]) or repair of thoracoabdominal aneurysm

EXC02 - Critical state immediately before surgery with high probability of death within 24 hours of surgery (e.g., acute aortic dissection, cardiac arrest within 24 hours before surgery)

EXC03 - Severe right heart failure (clinical diagnosis ± echocardiography)

EXC03 - Severe right heart failure (clinical diagnosis ± echocardiography)

EXC04 - Known contraindications to heparin

EXC05 - PCC required for reversal of warfarin or direct oral anticoagulant (DOAC; dabigatran, rivaroxaban, apixaban or edoxaban) within 3 days prior to or during surgery

EXC06 - Known thromboembolic event (TEE) within 3 months prior to surgery

EXC07 - History of severe allergic reactions to PCC or FP

EXC08 - Individuals who have immunoglobulin A (IgA) deficiency with known antibodies against IgA

EXC09 - Refusal of allogeneic blood products
EXC10 - Known pregnancy
EXC11 - Currently enrolled in other interventional clinical trials

Visit 1

Body Weight

[Revision: Revision 2]

(Visit ID = 20 / Visit Display Name = Visit 1 / Visit Abbrev = V1-D0 / PageID = 50 / Page Display Name = Body Weight / Description = Body Weight)

* Patient's Body Weight (kg) at Visit 1		(format xxx.x)

Informed Consent

[Revision: Revision 2]

(Visit ID = 20 / Visit Display Name = Visit 1 / Visit Abbrev = V1-D0 / PageID = 70 / Page Display Name = Informed Consent / Description = Informed Consent)

Please note that although this page appears within this visit this does not mean that this page must necessarily be completed during this visit. If informed consent has not yet been sought, please return to this page at a later date.

* Has the subject/SDM given informed consent?	○ Yes ○ No	
* Date informed consent was signed		(DD-MMM-YYYY)
* Time informed consent was signed		(HH24:MI)
* Protocol version consented to	○ 5.0 (US) - 12-Apr-2022 ○ 6.0 (Canada) - 12-Apr-2022	
* If no, did the subject/SDM:	○ Refuse ○ Not respond/Uncontactable ○ Patient expired before being approached ○ Other	
* Please specify the reason subject/SDM did not give informed consent		
* If no, has the REB given special permission to collect data for this subject?	○ Yes ○ No	
* Which data has the REB given permission to collect?	○ SAEs and hemostatic therapies ○ All Data	

Eligibility

[Revision: Revision 2]

(Visit ID = 20 / Visit Display Name = Visit 1 / Visit Abbrev = V1-D0 / PageID = 20 / Page Display Name = Eligibility / Description = Eligibility Criteria)

Note: Exclusion Criterion #3 in particular should be rechecked on the day of surgery

* Does the patient meet all of the inclusion criteria?
- ○ Yes
- ○ No

Multiple criteria can be selected by holding 'Ctrl' and clicking options below

* If No, indicate all criteria not met
- ☐ INC01
- ☐ INC02
- ☐ INC03
- ☐ INC04

* Does the patient meet any of the exclusion criteria?
- ○ Yes
- ○ No

Multiple criteria can be selected by holding 'Ctrl' and clicking options below

* If No, indicate all criteria met
- ☐ EXC01
- ☐ EXC02
- ☐ EXC03
- ☐ EXC04
- ☐ EXC05
- ☐ EXC06
- ☐ EXC07
- ☐ EXC08
- ☐ EXC09
- ☐ EXC10
- ☐ EXC11

Since the patient did not meet certain inclusion criteria and/or did meet certain exclusion criteria the patient is not eligible to enroll on this study. The below options are therefore not available, please save this page as is and then the patient will be recorded as a Screen Failure.

Based upon a review of the inclusion and exclusion criteria at this visit, the patient is eligible to continue on this study?	○ Yes ○ No
* If No, please specify reason	

Inclusion Criteria

INC01 - Adult (≥18 years old) patients undergoing any index cardiac surgery employing CPB

INC02 - Coagulation factor replacement with PCC or FP ordered in the operating room for: a.Management of bleeding, or b. Anticipated bleeding in a patient who has been on-pump for >2 hours or has undergone a complex procedure (e.g., aortocoronary bypass [ACB] plus aortic valve replacement)

INC03 - Coagulation factor deficiency, either known to exist (e.g., as indicated by elevated EXTEM clotting time [CT] or INR) or suspected based on the clinical situation

INC04 - Patients who have given written informed consent

Exclusion Criteria

EXC01 - Undergoing heart transplantation, insertion or removal of ventricular assist devices (not including intra-aortic balloon pump [IABP]) or repair of thoracoabdominal aneurysm

EXC02 - Critical state immediately before surgery with high probability of death within 24 hours of surgery (e.g., acute aortic dissection, cardiac arrest within 24 hours before surgery)

EXC03 - Severe right heart failure (clinical diagnosis ± echocardiography)

EXC03 - Severe right heart failure (clinical diagnosis ± echocardiography)

EXC04 - Known contraindications to heparin

EXC05 - PCC required for reversal of warfarin or direct oral anticoagulant (DOAC; dabigatran, rivaroxaban, apixaban or edoxaban) within 3 days prior to or during surgery

EXC06 - Known thromboembolic event (TEE) within 3 months prior to surgery

EXC07 - History of severe allergic reactions to PCC or FP

EXC08 - Individuals who have immunoglobulin A (IgA) deficiency with known antibodies against IgA

EXC09 - Refusal of allogeneic blood products
EXC10 - Known pregnancy
EXC11 - Currently enrolled in other interventional clinical trials

Randomization

[Revision: Revision 2]

(Visit ID = 20 / Visit Display Name = Visit 1 / Visit Abbrev = V1-D0 / PageID = 40 / Page Display Name = Randomization / Description = Randomization)

* Randomization Code		
* Date patient randomized		(DD-MMM-YYYY)
* Time patient randomized		(HH24:MI)
* Patient has been randomized into the following group:	○ Octaplex (PCC) ○ Frozen Plasma (FP)	

Subject Weight Information

Body Weight (kg)	(remote value)	
Patients body weight is greater than 60kg		
Patients body weight is less than or equal to 60kg		

IMP Preparation - First Dose

[Revision: Revision 2]

(Visit ID = 20 / Visit Display Name = Visit 1 / Visit Abbrev = V1-D0 / PageID = 60 / Page Display Name = IMP Preparation - First Dose / Description = IMP Preparation - First Dose - Revision 2)

Randomization Group patient has been assigned to:	(remote value)	
* Was the first dose of IMP released?	○ Yes ○ No	
* Date IMP released		(DD-MMM-YYYY)
* Time IMP released		(HH24:MI)
* Dose of IMP released	○ Octaplex [1500 IU] ○ Octaplex [2000 IU] ○ Frozen Plasma [3 units] ○ Frozen Plasma [4 units]	

If any IMP was prepared but not subsequently released, please record the batch details below (required for Octaplex only)

Batch Number	Number of vials in batch	Batch Amount (per vial)	Amount Returned (in total from each batch)
	(x)	○ 500 IU ○ 1000 IU	○ None ○ 500 IU ○ 1000 IU ○ 1500 IU ○ 2000 IU
	(x)	○ 500 IU ○ 1000 IU	○ None ○ 500 IU ○ 1000 IU ○ 1500 IU ○ 2000 IU
	(x)	○ 500 IU ○ 1000 IU	○ None ○ 500 IU ○ 1000 IU ○ 1500 IU ○ 2000 IU
	(x)	○ 500 IU ○ 1000 IU	○ None ○ 500 IU ○ 1000 IU ○ 1500 IU ○ 2000 IU

* If Octaplex was returned, was the seal broken? ○ Yes ○ No

* Was any of the released Frozen Plasma returned? ○ Yes ○ No

* If yes, please state how many units were returned ______ (format x)

* Was the released product different than the randomization?	○ Yes ○ No	
* If yes, please specify reason		
Total amount of Octaplex released for Administration (IU) (Amount released and not returned)	(auto calculated)	(format xxxxx)
Total amount of Frozen Plasma released for Administration (IU) (Amount released and not returned)	(auto calculated)	(format x)

Please note: Auto-calculated values do not update in real time, please save (or re-save) the page in order to get the correct value to appear above.

IMP Preparation - Second Dose

[Revision: Revision 2]

(Visit ID = 20 / Visit Display Name = Visit 1 / Visit Abbrev = V1-D0 / PageID = 80 / Page Display Name = IMP Preparation - Second Dose / Description = IMP Preparation - Second Dose - Revision 2)

Randomization Group patient has been assigned to:	(remote value)	
* Was the second dose of IMP released?	○ Yes ○ No	
* Date IMP released		(DD-MMM-YYYY)
* Time IMP released		(HH24:MI)
* Dose of IMP released	○ Octaplex [1500 IU] ○ Octaplex [2000 IU] ○ Frozen Plasma [3 units] ○ Frozen Plasma [4 units]	

If any IMP was prepared but not subsequently released, please record the batch details below (required for Octaplex only)

Batch Number	Number of vials in batch	Batch Amount (per vial)	Amount Returned (in total from each batch)
	(x)	○ 500 IU ○ 1000 IU	○ None ○ 500 IU ○ 1000 IU ○ 1500 IU ○ 2000 IU
	(x)	○ 500 IU ○ 1000 IU	○ None ○ 500 IU ○ 1000 IU ○ 1500 IU ○ 2000 IU
	(x)	○ 500 IU ○ 1000 IU	○ None ○ 500 IU ○ 1000 IU ○ 1500 IU ○ 2000 IU
	(x)	○ 500 IU ○ 1000 IU	○ None ○ 500 IU ○ 1000 IU ○ 1500 IU ○ 2000 IU

* If returned, was the seal broken? ○ Yes ○ No

* Was any of the released Frozen Plasma returned? ○ Yes ○ No

* If yes, please state how many units were returned ______ (format x)

* Was the released product different than the randomization?	○ Yes ○ No	
* If yes, please specify reason		
Total amount of Octaplex released for Administration (IU) (Amount released and not returned)	(auto calculated)	(format xxxxx)
Total amount of Frozen Plasma released for Administration (IU) (Amount released and not returned)	(auto calculated)	(format x)

Please note: Auto-calculated values do not update in real time, please save (or re-save) the page in order to get the correct value to appear above.

Clinical Chemistry - Baseline

[Revision: Revision 2]

(Visit ID = 20 / Visit Display Name = Visit 1 / Visit Abbrev = V1-D0 / PageID = 90 / Page Display Name = Clinical Chemistry - Baseline / Description = Labs - Clinical Chemistry - Revision 2)

* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

Please only record the last lab sample collected prior to surgery at this visit and record any other lab samples that were collected at this visit in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as a Medical History Entry

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Total Bilirubin	☐		(xxxxx.xxxxx)		○ µmol/L ○ mg/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Alanine Aminotransferase (ALT)	☐		(xxxxx.xxxxx)		○IU/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Alkaline Phosphatase (ALP) ☐		(xxxxx.xxxxx)		○ IU/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Creatinine	☐		(xxxxx.xxxxx)		○ µmol/L ○ mg/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Troponin I-hs	☐		(xxxxx.xxxxx)		○ mmol/L ○ ng/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Troponin T-hs	☐		(xxxxx.xxxxx)		○mmol/L ○ng/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Sodium	☐		(xxxxx.xxxxx)		○ mmol/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Potassium	☐		(xxxxx.xxxxx)		○mmol/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Chloride	☐		(xxxxx.xxxxx)		○ mmol/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Bicarbonate	☐		(xxxxx.xxxxx)		○ µmol/L ○ mmol/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank
pH	☐		(xxxxx.xxxxx)		○ None ○ Other			○ Yes ○ No	Only required for results outside of normal range, may be left blank

Haematology (CBC) - Baseline

[Revision: Revision 2]

(Visit ID = 20 / Visit Display Name = Visit 1 / Visit Abbrev = V1-D0 / PageID = 100 / Page Display Name = Haematology (CBC) - Baseline / Description = Labs - Hematology - Revision 2)

* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

Please only record the last lab sample collected prior to surgery at this visit and record any other lab samples that were collected at this visit in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as a Medical History Entry

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Hemoglobin (HGB)	☐		(xxxxx.xxxxx)		○ g/L ○ g/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Hematocrit (HCT)	☐		(xxxxx.xxxxx)		○L/L ○% ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Red Blood Cells (RBC)	☐		(xxxxx.xxxxx)		○ 10^12/L ○ M/mm3 ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Platelets	☐		(xxxxx.xxxxx)		○10^9/L ○K/mm3 ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

White Blood Cells (WBC)	☐		(xxxxx.xxxxx)		○ 10^9/L ○ K/mm3 ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Coagulation Measures - Coag. - Baseline

[Revision: Revision 2]

(Visit ID = 20 / Visit Display Name = Visit 1 / Visit Abbrev = V1-D0 / PageID = 110 / Page Display Name = Coagulation Measures - Coag. - Baseline / Description = Labs - Coagulation - Coag. - Revision 2)

Coagulation		
* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

Please only record the last lab sample collected prior to surgery at this visit and record any other lab samples that were collected at this visit in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as a Medical History Entry

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Prothrombin Time (PT)	☐		(xxxxx.xxxxx)		○ Seconds ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Activated Partial Thomboplasin Time (aPTT)	☐		(xxxxx.xxxxx)		○Seconds ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

INR	☐		(xxxxx.xxxxx)		○ Ratio ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Fibrinogen	☐		(xxxxx.xxxxx)		○ g/L ○ mg/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Visit 2 (POD 0)

Demographics

[Revision: Revision 2]

(Visit ID = 30 / Visit Display Name = Visit 2 (POD 0) / Visit Abbrev = V2-D0 / PageID = 30 / Page Display Name = Demographics / Description = Demographics)

* Age at time of surgery		(format xx)
* Sex	○ Male ○ Female ○ Other	
* If Other, please specify		
Height & Weight Information		
* Height		(format xxx.x)
* Height Unit	○ cm ○ in	
Weight (kg)	(remote value)	
Body Mass Index (BMI)	(auto calculated)	(format xx.x)
Ethnicity. Do you consider yourself Hispanic/Latino or not Hispanic/Latino?	○ Hispanic/Latino Heritage ○ Not Hispanic/Latino Heritage ○ Unknown	
Race: Check all that apply		
Subject refused to answer	☐	
American Indian or Alaska Native	☐	A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment.

Asian	☐	A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent, including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.
Black or African American	☐	A person having origins in any of the black racial groups of Africa. Terms such as “Haitian” or “Negro” can be used in addition to “Black or African American.”
Native Hawaiian or Other Pacific Islanders	☐	A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.
White	☐	A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
Not Known	☐	This option should be selected if the information is not recorded anywhere and staff are unable to communicate with the patient/SDM.
Other	☐	This option should be selected if the patient’s ethnicity is not described or includes another ethnicity in addition to what is listed above
* If Other, please specify		

Co-morbidities

[Revision: Revision 2]

(Visit ID = 30 / Visit Display Name = Visit 2 (POD 0) / Visit Abbrev = V2-D0 / PageID = 180 / Page Display Name = Co-morbidities / Description = Co-morbidities)

* NYHA classification	○ I ○ II ○ III ○ IV
* Myocardial Infarction	○ No ○ < 7 days ○ 7-29 days ○ 30-90 days ○ More than 90 days ○ Unknown
* Left Ventrical Function	○ Good (EF>50%) ○ Moderate (EF 50%-31%) ○ Poor (EF 30%-21%) ○ Very poor (EF<21%) ○ Unknown
* Diabetis Mellitus	○ No ○ Type I ○ Type II ○ Type II (on insulin)
* Pulmonary Hypertension	○ No ○ Moderate (PAs 31-55) ○ Severe (PAs >55) ○ Unknown

* On Dialysis	○	Yes
	○	No
* Previous Cardiac Surgery	○	Yes
	○	No
* Chronic Lung disease	○	Yes
	○	No
* PVD	○	Yes
	○	No
* Active Endocarditis	○	Yes
	○	No
* CCS Class 4 Angina	○	Yes
	○	No
* CVA/TIA	○	Yes
	○	No
* IABP	○	Yes
	○	No
* Dyslipidemia	○	Yes
	○	No
* Hypertension	○	Yes
	○	No
* Artrial Fibrillation	○	Yes
	○	No
* Neurological Dysfunction	○	Yes
	○	No
* CHF	○	Yes
	○	No
* Ventrical Assist Device/ECMO	○	Yes
	○	No

* Other	○	Yes
	○	No
If Yes, please ensure any other co-morbidities are recorded under Medical History		
* Preoperative ECG performed?	○	Yes
	○	No
* ECG Result	○	Normal
	○	Abnormal
If Result Abnormal, please specify (tick all that apply)		
ST Elevation	☐	
Q Waves	☐	
LBBB	☐	
Other	☐	
* If Other, please specify		

Medical History

[Revision: Revision 2]

(Visit ID = 30 / Visit Display Name = Visit 2 (POD 0) / Visit Abbrev = V2-D0 / PageID = 40 (*) / Page Display Name = Medical History / Description = Medical History - Revision 2)

* Medical History Condition		
* Start Date		(UNK-UNK-UNK)
Ongoing?	○ Yes ○ No	
End Date		(UNK-UNK-UNK)

Pre-Operative Anti-Coagulation Medication

[Revision: Revision 2]

(Visit ID = 30 / Visit Display Name = Visit 2 (POD 0) / Visit Abbrev = V2-D0 / PageID = 50 (*) / Page Display Name = Pre-Operative Anti-Coagulation Medication / Description = Pre-operative Anti-Coagulation Medication)

* Medication	○ Abciximab (Reopro) ○ Apixaban (Eliquis) ○ ASA ○ Clopidogrel (Plavix) ○ Dabigatran (Pradaxa) ○ Edoxaban (Lixiana) ○ Glycoprotein IIa/IIb inhibitor ○ Heparin Unfractionated ○ LMWH ○ Prasugrel (Effient) ○ Rivaroxaban (Xarelto) ○ Ticagrelor (Brilinta) ○ Ticlopidine (Ticlid) ○ Tirofiban (Aggrastat) ○ Warfarin (Counmadin) ○ Other	
* If Other, please specify		
Date of intake		(DD-MMM-YYYY)
Time of intake		(HH24:MI)
* Total daily dose		(format xxxxx.x)

* Unit	○ mg ○ U ○ µg/kg/min ○ units/hr ○ Other	
* If Other, please specify		
* Discontinued before surgery?	○ Yes ○ No	
* If Yes, Date		(DD-MMM-YYYY)

Initial Surgery

[Revision: Revision 2]

(Visit ID = 30 / Visit Display Name = Visit 2 (POD 0) / Visit Abbrev = V2-D0 / PageID = 60 / Page Display Name = Initial Surgery / Description = Surgery - Revision 2)

Surgical Procedure performed (check all that apply)		
ACB x	☐	
* # of Coronaries		(format xx)
AV repair/replace	☐	
MV repair/replace	☐	
TV repair/replace	☐	
PV repair/replace	☐	
Myectomy	☐	
ASD repair	☐	
VSD repair	☐	
LV Aneurysmectomy	☐	
Complex Congenital	☐	
Maze	☐	
ECMO insertion	☐	
IABP insertion	☐	
LVAD/RVAD insertion	☐	
Surgery on Aorta (check all that apply):		
Ascending	☐	
Arch	☐	
Descending	☐	
Other	☐	
* If Other, please specify		
Procedure Details		

* Reason for procedure	○ Surgical Re-exploration ○ Other	
* Cause of re-exploration	○ Bleeding ○ Tamponade ○ Other	
* If Other, please specify		
* Other reason for procedure		
* Surgical procedure performed		
* Urgency	○ Elective ○ Urgent ○ Emergency	
* Start date of surgery		(DD-MMM-YYYY)
* Start time of surgery		(HH24:MI)
End date of surgery is different to the start date of the surgery	☐	
* End date of surgery		(DD-MMM-YYYY)
* End time of surgery		(HH24:MI)
Dosing details		
Total heparin dose (U)		(format xxxxx.x)
Total protamine dose (mg)		(format xxxxx.x)
Please enter either Tranexamic acid dose or Aminocaproic acid dose below.		
Total tranexamic acid (TXA) dose (U)		(format xxxxx.x)
Total Aminocaproic acid dose		(format xxxxx.x)

Total Aminocaproic acid dose unit	○ g ○ mg ○ Other	
Unit, Other		
ACT: Pre heparin (sec)		(format xxxxx.x)
ACT: Post heparin (sec)		(format xxxxx.x)
ACT: Post protamine (sec)		(format xxxxx.x)
Cardiopulmonary Bypass		
* Did the patient undergo CPB during surgery?	○ Yes ○ No	
Start date of CPB is different to the start date of the surgery	☐	
* Initial start date of CPB		(DD-MMM-YYYY)
* Initial start time of CPB		(HH24:MI)
Final end date of CPB is different to the start date of the surgery	☐	
* Final end date of CPB		(DD-MMM-YYYY)
* Final end time of CPB		(HH24:MI)
* CPB duration (minutes)		(format xxxxx.x)
* CPB Pump prime (mL)		(format xxxxx.x)
Fluid intake and output		
* Cell Salvage?	○ Yes ○ No	
* Blood collected (ml)		(format xxxxx.x)
* Blood returned (ml)		(format xxxxx.x)

Duration Details		
Cross clamp not applicable in this surgery	☐	
* Total Cross-clamp duration (minutes)		(format xxxxx.x)
Circulatory arrest not applicable in this surgery	☐	
* Circulatory arrest duration (minutes)		(format xxxxx.x)
Intubation/Extubation		
Intubation/Extubation not applicable in this surgery	☐	
Intubation date is different to the start date of the surgery	☐	
* Intubation Date		(DD-MMM-YYYY)
* Intubation Time		(HH24:MI)
Extubation date is different to the start date of the surgery	☐	
* Extubation Date		(DD-MMM-YYYY)
* Extubation Time		(HH24:MI)
Total intubation duration (minutes)	(auto calculated)	(format xxxx)

IMP Administration - First Dose

[Revision: Revision 2]

(Visit ID = 30 / Visit Display Name = Visit 2 (POD 0) / Visit Abbrev = V2-D0 / PageID = 20 / Page Display Name = IMP Administration - First Dose / Description = Transfusions - First IMP)

First IMP Transfusion		
* Start date of transfusion		(DD-MMM-YYYY)
* Start time of transfusion		(HH24:MI)
End time of transfusion was not recorded	☐	
End date of transfusion is different to the start date of transfusion	☐	
* End date of transfusion		(DD-MMM-YYYY)
* End time of transfusion		(HH24:MI)
Transfusion Duration (mins)	(auto calculated)	(format xxxxx.xx)
* Transfusion was administered appropriately?	○ Yes ○ No	
* Please provide details as to why the transfusion was not administered appropriately		

Bleeding Score	
* Bleeding Score	○ 1 ○ 2 ○ 3 ○ 4

Parameter	Timepoint	Not Done?	Reason not done	Result	Unit	Unit, Other	Collection Date is different to Start Date of Transfusion	Collection Date	Collection Time
INR	Within 30 mins before IMP administration	☐		(xxxx.xx)	○ Ratio ○ Other		☐	(DD-MMM-YYYY)	(HH24:MI)
INR	At 60 mins after IMP administration	☐		(xxxx.xx)	○ Ratio ○ Other		☐	(DD-MMM-YYYY)	(HH24:MI)
Haemoglobin	Within 30 mins before IMP administration	☐		(xxxx.xx)	○ g/L ○ Other		☐	(DD-MMM-YYYY)	(HH24:MI)
Haemoglobin	At 60 mins after IMP administration	☐		(xxxx.xx)	○ g/L ○ Other		☐	(DD-MMM-YYYY)	(HH24:MI)
Haemoglobin	At 24 hrs after IMP administration	☐		(xxxx.xx)	○ g/L ○ Other		☐	(DD-MMM-YYYY)	(HH24:MI)

IMP Administration - Second Dose

[Revision: Revision 2]

(Visit ID = 30 / Visit Display Name = Visit 2 (POD 0) / Visit Abbrev = V2-D0 / PageID = 200 / Page Display Name = IMP Administration - Second Dose / Description = Transfusions - Second IMP - Revision 2)

Second IMP Transfusion		
* Start date of transfusion		(DD-MMM-YYYY)
* Start time of transfusion		(HH24:MI)
End time of transfusion was not recorded	☐	
End date of transfusion is different to the start date of transfusion	☐	
* End date of transfusion		(DD-MMM-YYYY)
* End time of transfusion		(HH24:MI)
Transfusion Duration (mins)	(auto calculated)	(format xxxxx.xx)
* Transfusion was administered appropriately?	○ Yes ○ No	
* Please provide details as to why the transfusion was not administered appropriately		

Bleeding Score		
Bleeding Score not done	☐	
Please provide details as to why bleeding score was not done		

* Bleeding Score

- ○ 1
- ○ 2
- ○ 3
- ○ 4

Parameter	Timepoint	Not Done?	Reason not done	Result	Unit	Unit, Other	Collection Date is different to Start Date of Transfusion	Collection Date	Collection Time
INR	Prior to Second IMP administration	☐		(xxxx.xx)	○ Ratio ○ Other		☐	(DD-MMM-YYYY)	(HH24:MI)

Other Transfusions

[Revision: Revision 2]

(Visit ID = 30 / Visit Display Name = Visit 2 (POD 0) / Visit Abbrev = V2-D0 / PageID = 230 (*) / Page Display Name = Other Transfusions / Description = Transfusions - Non-IMP - Revision 2)

Transfusion		
Transfusion type	○ Albumin ○ Cryoprecipitate ○ Factor VIIa ○ Fibrinogen Concentrate ○ PCC (Other than IMP) ○ FP-Apheresis (Other than IMP) ○ FP-Non-Apheresis (Other than IMP) ○ Platelets-Apheresis ○ Platelets-Non-Apheresis ○ Red Blood Cells ○ Other	
* PCC Type	○ Octaplex ○ Other	
* Product Name		
* Start date of transfusion		(DD-MMM-YYYY)
* Start time of transfusion		(HH24:MI)
End time of transfusion was not recorded	☐	
End date of transfusion is different to the start date of transfusion	☐	
* End date of transfusion		(DD-MMM-YYYY)

* End time of transfusion		(HH24:MI)
Transfusion Duration (mins)	(auto calculated)	(format xxxxx.xx)
* Albumin Strength (%)	○ 5% ○ 25% ○ Other	
* Albumin Strength (%), Other		(format xxxxx.x)
* Amount administered		(format xxxxx.x)
* Unit		
Amount Administered (Albumin) Units: mL *Amount Administered (Cryoprecipitate) Units: mL* *Amount Administered (Factor VIIa) Units: mg* *Amount Administered (Fibrinogen Concentrate) Units: g* *Amount Administered (PCC) Units: IU* *Amount Administered (Frozen Plasma) Units: U* *Amount Administered (Platelets) Units: U* *Amount Administered (Red Blood Cells) Units: U*		
* Relation to initial surgery	○ Between surgery start & 24hr later ○ Between 24h post surg. start and POD 7 ○ Other	1) Within 60 minutes to 24 hours after start of surgery 2) Between 24 hours post-surgery start and Post-Operative Day 7 3) Other
* Other		
* Transfusion was administered appropriately?	○ Yes ○ No	

* Please provide details as to why the transfusion was not administered appropriately	

Total Chest Tube Blood Loss

[Revision: Revision 2]

(Visit ID = 30 / Visit Display Name = Visit 2 (POD 0) / Visit Abbrev = V2-D0 / PageID = 130 / Page Display Name = Total Chest Tube Blood Loss / Description = Cumulative Chest Tube Blood Loss)

Chest tubes were not inserted	☐	
* Cumulative chest tube blood loss at ICU admission (mL):		(format xxxxx)
Chest tubes were removed before 1 hour post operation	☐	
* Cumulative chest tube blood loss at 1 hour post-operatively (mL):		(format xxxxx)
Chest tubes were removed before 6 hours post operation	☐	
* Cumulative chest tube blood loss at 6 hours post-operatively (mL):		(format xxxxx)
Chest tubes were removed before 12 hours post operation	☐	
* Cumulative chest tube blood loss at 12 hours post-operatively (mL):		(format xxxxx)
Chest tubes were removed before 24 hours post operation	☐	
* Cumulative chest tube blood loss at 24 hours post-operatively (mL):		(format xxxxx)
Chest tubes removal		
Date chest tubes were removed is different to the start date of the surgery	☐	
* Date chest tubes were removed		(DD-MMM-YYYY)
* Time chest tubes were removed		(HH24:MI)

Cumulative chest tube blood loss when tubes were removed (mL):		(format xxxxx)
Chest tube duration (mins)	(auto calculated)	(format xxxxxx)

Haemorrhages

[Revision: Revision 2]

(Visit ID = 30 / Visit Display Name = Visit 2 (POD 0) / Visit Abbrev = V2-D0 / PageID = 150 (*) / Page Display Name = Haemorrhages / Description = Haemorrhage)

Only haemorrhages that occur within 0-24 hrs after surgery should be recorded here, any that occur after surgery should be captured as an AE.

* Type of Haemorrhage	○ Intracerebral Haemorrhage ○ Gastrointestinal Haemorrhage ○ Other	
* Type, Other		
* Start date of Haemorrhage		(DD-MMM-YYYY)
* Start time of Haemorrhage		(HH24:MI)
End date of haemorrhage is different to the start date of haemorrhage	☐	
* End date of Haemorrhage		(DD-MMM-YYYY)
* End time of Haemorrhage		(HH24:MI)

Clinical Chemistry

[Revision: Revision 2]

(Visit ID = 30 / Visit Display Name = Visit 2 (POD 0) / Visit Abbrev = V2-D0 / PageID = 70 / Page Display Name = Clinical Chemistry / Description = Labs - Clinical Chemistry - Revision 2)

* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

Please only record the last lab sample collected prior to surgery at this visit and record any other lab samples that were collected at this visit in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as a Medical History Entry

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Total Bilirubin	☐		(xxxxx.xxxxx)		○ µmol/L ○ mg/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Alanine Aminotransferase (ALT)	☐		(xxxxx.xxxxx)		○IU/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Alkaline Phosphatase (ALP)	☐		(xxxxx.xxxxx)		○ IU/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Creatinine	☐		(xxxxx.xxxxx)		○ µmol/L ○ mg/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Troponin I-hs	☐		(xxxxx.xxxxx)		○mmol/L ○ng/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Troponin T-hs	☐		(xxxxx.xxxxx)		○mmol/L ○ng/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Sodium	☐		(xxxxx.xxxxx)		○mmol/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Potassium	☐		(xxxxx.xxxxx)		○mmol/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Chloride	☐		(xxxxx.xxxxx)		○mmol/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Bicarbonate	☐		(xxxxx.xxxxx)		○ µmol/L ○ mmol/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank
pH	☐		(xxxxx.xxxxx)		○ None ○ Other			○ Yes ○ No	Only required for results outside of normal range, may be left blank

Haematology (CBC)

[Revision: Revision 2]

(Visit ID = 30 / Visit Display Name = Visit 2 (POD 0) / Visit Abbrev = V2-D0 / PageID = 80 / Page Display Name = Haematology (CBC) / Description = Labs - Hematology - Revision 2)

* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

Please only record the last lab sample collected prior to surgery at this visit and record any other lab samples that were collected at this visit in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as a Medical History Entry

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Hemoglobin (HGB)	☐		(xxxxx.xxxxx)		○ g/L ○ g/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Hematocrit (HCT)	☐		(xxxxx.xxxxx)		○L/L ○% ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Red Blood Cells (RBC)	☐		(xxxxx.xxxxx)		○ 10^12/L ○ M/mm3 ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Platelets	☐		(xxxxx.xxxxx)		○10^9/L ○K/mm3 ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

White Blood Cells (WBC)	☐		(xxxxx.xxxxx)		○ 10^9/L ○ K/mm3 ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Coagulation Measures - Coag.

[Revision: Revision 2]

(Visit ID = 30 / Visit Display Name = Visit 2 (POD 0) / Visit Abbrev = V2-D0 / PageID = 90 / Page Display Name = Coagulation Measures - Coag. / Description = Labs - Coagulation - Coag. - Revision 2)

Coagulation		
* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

Please only record the last lab sample collected prior to surgery at this visit and record any other lab samples that were collected at this visit in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as a Medical History Entry

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Prothrombin Time (PT)	☐		(xxxxx.xxxxx)		○Seconds ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Activated Partial Thomboplasin Time (aPTT)	☐		(xxxxx.xxxxx)		○Seconds ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

INR	☐		(xxxxx.xxxxx)		○ Ratio ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Fibrinogen	☐		(xxxxx.xxxxx)		○ g/L ○ mg/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Coagulation Measures - ROTEM

[Revision: Revision 2]

(Visit ID = 30 / Visit Display Name = Visit 2 (POD 0) / Visit Abbrev = V2-D0 / PageID = 210 / Page Display Name = Coagulation Measures - ROTEM / Description = Labs - Coagulation - ROTEM - Revision 2)

ROTEM		
* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
ROTEM EXTEM CT	☐		(xxxxx.xxxxx)		○ Seconds ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

ROTEM EXTEM MCF	☐		(xxxxx.xxxxx)		○mm ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

ROTEM FIBTEM MCF	☐		(xxxxx.xxxxx)		○ mm ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Coagulation Measures - Platelets

[Revision: Revision 2]

(Visit ID = 30 / Visit Display Name = Visit 2 (POD 0) / Visit Abbrev = V2-D0 / PageID = 220 / Page Display Name = Coagulation Measures - Platelets / Description = Labs - Coagulation - Platelets - Revision 2)

Platelets		
* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Platelet Count	☐		(xxxxx.xxxxx)		○ µL ○ 10^9/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Platelet Function	☐		(xxxxx.xxxxx)		○mg/dL ○% ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Visit 2 (POD 1)

Clinical Chemistry

[Revision: Revision 2]

(Visit ID = 140 / Visit Display Name = Visit 2 (POD 1) / Visit Abbrev = V2-D1 / PageID = 10 / Page Display Name = Clinical Chemistry / Description = Labs - Clinical Chemistry - Revision 2)

* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

Please only record the last lab sample collected prior to surgery at this visit and record any other lab samples that were collected at this visit in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as a Medical History Entry

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Total Bilirubin	☐		(xxxxx.xxxxx)		○ µmol/L ○ mg/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Alanine Aminotransferase (ALT)	☐		(xxxxx.xxxxx)		○IU/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Alkaline Phosphatase (ALP) ☐		(xxxxx.xxxxx)		○IU/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Creatinine	☐		(xxxxx.xxxxx)		○ µmol/L ○ mg/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Troponin I-hs	☐		(xxxxx.xxxxx)		○ mmol/L ○ ng/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Troponin T-hs	☐		(xxxxx.xxxxx)		○mmol/L ○ng/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Sodium	☐		(xxxxx.xxxxx)		○mmol/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Potassium	☐		(xxxxx.xxxxx)		○ mmol/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Chloride	☐		(xxxxx.xxxxx)		○mmol/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Bicarbonate	☐		(xxxxx.xxxxx)		○ µmol/L ○ mmol/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank
pH	☐		(xxxxx.xxxxx)		○ None ○ Other			○ Yes ○ No	Only required for results outside of normal range, may be left blank

Haematology (CBC)

[Revision: Revision 2]

(Visit ID = 140 / Visit Display Name = Visit 2 (POD 1) / Visit Abbrev = V2-D1 / PageID = 20 / Page Display Name = Haematology (CBC) / Description = Labs - Hematology - Revision 2)

* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

Please only record the last lab sample collected prior to surgery at this visit and record any other lab samples that were collected at this visit in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as a Medical History Entry

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Hemoglobin (HGB)	☐		(xxxxx.xxxxx)		○ g/L ○ g/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Hematocrit (HCT)	☐		(xxxxx.xxxxx)		○L/L ○% ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Red Blood Cells (RBC)	☐		(xxxxx.xxxxx)		○ 10^12/L ○ M/mm3 ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Platelets	☐		(xxxxx.xxxxx)		○10^9/L ○K/mm3 ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

White Blood Cells (WBC)	☐		(xxxxx.xxxxx)		○ 10^9/L ○ K/mm3 ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Coagulation Measures - Coag.

[Revision: Revision 2]

(Visit ID = 140 / Visit Display Name = Visit 2 (POD 1) / Visit Abbrev = V2-D1 / PageID = 30 / Page Display Name = Coagulation Measures - Coag. / Description = Labs - Coagulation - Coag. - Revision 2)

Coagulation		
* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

Please only record the last lab sample collected prior to surgery at this visit and record any other lab samples that were collected at this visit in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as a Medical History Entry

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Prothrombin Time (PT)	☐		(xxxxx.xxxxx)		○ Seconds ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Activated Partial Thomboplasin Time (aPTT)	☐		(xxxxx.xxxxx)		○Seconds ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

INR	☐		(xxxxx.xxxxx)		○ Ratio ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Fibrinogen	☐		(xxxxx.xxxxx)		○ g/L ○ mg/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Coagulation Measures - ROTEM

[Revision: Revision 2]

(Visit ID = 140 / Visit Display Name = Visit 2 (POD 1) / Visit Abbrev = V2-D1 / PageID = 110 / Page Display Name = Coagulation Measures - ROTEM / Description = Labs - Coagulation - ROTEM - Revision 2)

ROTEM		
* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
ROTEM EXTEM CT	☐		(xxxxx.xxxxx)		○ Seconds ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

ROTEM EXTEM MCF	☐		(xxxxx.xxxxx)		○mm ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

ROTEM FIBTEM MCF	☐		(xxxxx.xxxxx)		○ mm ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Coagulation Measures - Platelets

[Revision: Revision 2]

(Visit ID = 140 / Visit Display Name = Visit 2 (POD 1) / Visit Abbrev = V2-D1 / PageID = 120 / Page Display Name = Coagulation Measures - Platelets / Description = Labs - Coagulation - Platelets - Revision 2)

Platelets		
* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Platelet Count	☐		(xxxxx.xxxxx)		○ µL ○ 10^9/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Platelet Function	☐		(xxxxx.xxxxx)		○mg/dL ○% ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Visit 3 (POD 2)

Clinical Chemistry

[Revision: Revision 2]

(Visit ID = 50 / Visit Display Name = Visit 3 (POD 2) / Visit Abbrev = V3-D2 / PageID = 10 / Page Display Name = Clinical Chemistry / Description = Labs - Clinical Chemistry - Revision 2)

* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

Please only record the last lab sample collected prior to surgery at this visit and record any other lab samples that were collected at this visit in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as a Medical History Entry

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Total Bilirubin	☐		(xxxxx.xxxxx)		○ µmol/L ○ mg/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Alanine Aminotransferase (ALT)	☐		(xxxxx.xxxxx)		○IU/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Alkaline Phosphatase (ALP) ☐		(xxxxx.xxxxx)		○IU/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Creatinine	☐		(xxxxx.xxxxx)		○ µmol/L ○ mg/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Troponin I-hs	☐		(xxxxx.xxxxx)		○mmol/L ○ng/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Troponin T-hs	☐		(xxxxx.xxxxx)		○mmol/L ○ng/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Sodium	☐		(xxxxx.xxxxx)		○ mmol/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Potassium	☐		(xxxxx.xxxxx)		○mmol/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Chloride	☐		(xxxxx.xxxxx)		○mmol/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Bicarbonate	☐		(xxxxx.xxxxx)		○ µmol/L ○ mmol/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank
pH	☐		(xxxxx.xxxxx)		○ None ○ Other			○ Yes ○ No	Only required for results outside of normal range, may be left blank

Haematology (CBC)

[Revision: Revision 2]

(Visit ID = 50 / Visit Display Name = Visit 3 (POD 2) / Visit Abbrev = V3-D2 / PageID = 20 / Page Display Name = Haematology (CBC) / Description = Labs - Hematology - Revision 2)

* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

Please only record the last lab sample collected prior to surgery at this visit and record any other lab samples that were collected at this visit in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as a Medical History Entry

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Hemoglobin (HGB)	☐		(xxxxx.xxxxx)		○ g/L ○ g/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Hematocrit (HCT)	☐		(xxxxx.xxxxx)		○L/L ○% ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Red Blood Cells (RBC)	☐		(xxxxx.xxxxx)		○ 10^12/L ○ M/mm3 ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Platelets	☐		(xxxxx.xxxxx)		○10^9/L ○K/mm3 ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

White Blood Cells (WBC)	☐		(xxxxx.xxxxx)		○ 10^9/L ○ K/mm3 ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Coagulation Measures - Coag.

[Revision: Revision 2]

(Visit ID = 50 / Visit Display Name = Visit 3 (POD 2) / Visit Abbrev = V3-D2 / PageID = 30 / Page Display Name = Coagulation Measures - Coag. / Description = Labs - Coagulation - Coag. - Revision 2)

Coagulation		
* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

Please only record the last lab sample collected prior to surgery at this visit and record any other lab samples that were collected at this visit in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as a Medical History Entry

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Prothrombin Time (PT)	☐		(xxxxx.xxxxx)		○Seconds ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Activated Partial Thomboplasin Time (aPTT)	☐		(xxxxx.xxxxx)		○Seconds ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

INR	☐		(xxxxx.xxxxx)		○ Ratio ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Fibrinogen	☐		(xxxxx.xxxxx)		○ g/L ○ mg/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Coagulation Measures - ROTEM

[Revision: Revision 2]

(Visit ID = 50 / Visit Display Name = Visit 3 (POD 2) / Visit Abbrev = V3-D2 / PageID = 110 / Page Display Name = Coagulation Measures - ROTEM / Description = Labs - Coagulation - ROTEM - Revision 2)

ROTEM		
* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
ROTEM EXTEM CT	☐		(xxxxx.xxxxx)		○Seconds ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

ROTEM EXTEM MCF	☐		(xxxxx.xxxxx)		○mm ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

ROTEM FIBTEM MCF	☐		(xxxxx.xxxxx)		○ mm ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Coagulation Measures - Platelets

[Revision: Revision 2]

(Visit ID = 50 / Visit Display Name = Visit 3 (POD 2) / Visit Abbrev = V3-D2 / PageID = 120 / Page Display Name = Coagulation Measures - Platelets / Description = Labs - Coagulation - Platelets - Revision 2)

Platelets		
* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Platelet Count	☐		(xxxxx.xxxxx)		○ µL ○ 10^9/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Platelet Function	☐		(xxxxx.xxxxx)		○mg/dL ○% ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Visit 3 (POD 3)

Clinical Chemistry

[Revision: Revision 2]

(Visit ID = 80 / Visit Display Name = Visit 3 (POD 3) / Visit Abbrev = V3-D3 / PageID = 10 / Page Display Name = Clinical Chemistry / Description = Labs - Clinical Chemistry - Revision 2)

* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

Please only record the last lab sample collected prior to surgery at this visit and record any other lab samples that were collected at this visit in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as a Medical History Entry

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Total Bilirubin	☐		(xxxxx.xxxxx)		○ µmol/L ○ mg/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Alanine Aminotransferase (ALT)	☐		(xxxxx.xxxxx)		○IU/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Alkaline Phosphatase (ALP)	☐		(xxxxx.xxxxx)		○IU/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Creatinine	☐		(xxxxx.xxxxx)		μmol/L mg/dL Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		Yes No	Only required for results outside of normal range, may be left blank

Troponin I-hs	☐		(xxxxx.xxxxx)		○ mmol/L ○ ng/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Troponin T-hs	☐		(xxxxx.xxxxx)		○mmol/L ○ng/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Sodium	☐		(xxxxx.xxxxx)		○ mmol/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Potassium	☐		(xxxxx.xxxxx)		○ mmol/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Chloride	☐		(xxxxx.xxxxx)		○ mmol/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Bicarbonate	☐		(xxxxx.xxxxx)		○ µmol/L ○ mmol/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank
pH	☐		(xxxxx.xxxxx)		○ None ○ Other			○ Yes ○ No	Only required for results outside of normal range, may be left blank

Haematology (CBC)

[Revision: Revision 2]

(Visit ID = 80 / Visit Display Name = Visit 3 (POD 3) / Visit Abbrev = V3-D3 / PageID = 20 / Page Display Name = Haematology (CBC) / Description = Labs - Hematology - Revision 2)

* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

Please only record the last lab sample collected prior to surgery at this visit and record any other lab samples that were collected at this visit in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as a Medical History Entry

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Hemoglobin (HGB)	☐		(xxxxx.xxxxx)		○ g/L ○ g/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Hematocrit (HCT)	☐		(xxxxx.xxxxx)		○L/L ○% ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Red Blood Cells (RBC)	☐		(xxxxx.xxxxx)		10^12/L M/mm3 Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		Yes No	Only required for results outside of normal range, may be left blank

Platelets	☐		(xxxxx.xxxxx)		○10^9/L ○K/mm3 ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

White Blood Cells (WBC)	☐		(xxxxx.xxxxx)		○ 10^9/L ○ K/mm3 ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Coagulation Measures - Coag.

[Revision: Revision 2]

(Visit ID = 80 / Visit Display Name = Visit 3 (POD 3) / Visit Abbrev = V3-D3 / PageID = 30 / Page Display Name = Coagulation Measures - Coag. / Description = Labs - Coagulation - Coag. - Revision 2)

Coagulation		
* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

Please only record the last lab sample collected prior to surgery at this visit and record any other lab samples that were collected at this visit in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as a Medical History Entry

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Prothrombin Time (PT)	☐		(xxxxx.xxxxx)		○Seconds ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Activated Partial Thomboplasin Time (aPTT)	☐		(xxxxx.xxxxx)		○Seconds ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

INR	☐		(xxxxx.xxxxx)		○ Ratio ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Fibrinogen	☐		(xxxxx.xxxxx)		○ g/L ○ mg/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Coagulation Measures - ROTEM

[Revision: Revision 2]

(Visit ID = 80 / Visit Display Name = Visit 3 (POD 3) / Visit Abbrev = V3-D3 / PageID = 40 / Page Display Name = Coagulation Measures - ROTEM / Description = Labs - Coagulation - ROTEM - Revision 2)

ROTEM		
* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
ROTEM EXTEM CT	☐		(xxxxx.xxxxx)		○Seconds ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

ROTEM EXTEM MCF	☐		(xxxxx.xxxxx)		○mm ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

ROTEM FIBTEM MCF	☐		(xxxxx.xxxxx)		○ mm ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Coagulation Measures - Platelets

[Revision: Revision 2]

(Visit ID = 80 / Visit Display Name = Visit 3 (POD 3) / Visit Abbrev = V3-D3 / PageID = 50 / Page Display Name = Coagulation Measures - Platelets / Description = Labs - Coagulation - Platelets - Revision 2)

Platelets		
* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Platelet Count	☐		(xxxxx.xxxxx)		○ µL ○ 10^9/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Platelet Function	☐		(xxxxx.xxxxx)		○mg/dL ○% ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Visit 3 (POD 4)

Clinical Chemistry

[Revision: Revision 2]

(Visit ID = 90 / Visit Display Name = Visit 3 (POD 4) / Visit Abbrev = V3-D4 / PageID = 10 / Page Display Name = Clinical Chemistry / Description = Labs - Clinical Chemistry - Revision 2)

* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

Please only record the last lab sample collected prior to surgery at this visit and record any other lab samples that were collected at this visit in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as a Medical History Entry

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Total Bilirubin	☐		(xxxxx.xxxxx)		○ µmol/L ○ mg/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Alanine Aminotransferase (ALT)	☐		(xxxxx.xxxxx)		○IU/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Alkaline Phosphatase (ALP) ☐		(xxxxx.xxxxx)		○IU/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Creatinine	☐		(xxxxx.xxxxx)		○ µmol/L ○ mg/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Troponin I-hs	☐		(xxxxx.xxxxx)		○mmol/L ○ng/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Troponin T-hs	☐		(xxxxx.xxxxx)		○mmol/L ○ng/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Sodium	☐		(xxxxx.xxxxx)		○ mmol/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Potassium	☐		(xxxxx.xxxxx)		○ mmol/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Chloride	☐		(xxxxx.xxxxx)		○ mmol/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Bicarbonate	☐		(xxxxx.xxxxx)		○µmol/L ○mmol/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank
pH	☐		(xxxxx.xxxxx)		○None ○Other			○Yes ○No	Only required for results outside of normal range, may be left blank

Haematology (CBC)

[Revision: Revision 2]

(Visit ID = 90 / Visit Display Name = Visit 3 (POD 4) / Visit Abbrev = V3-D4 / PageID = 20 / Page Display Name = Haematology (CBC) / Description = Labs - Hematology - Revision 2)

* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

Please only record the last lab sample collected prior to surgery at this visit and record any other lab samples that were collected at this visit in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as a Medical History Entry

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Hemoglobin (HGB)	☐		(xxxxx.xxxxx)		○ g/L ○ g/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Hematocrit (HCT)	☐		(xxxxx.xxxxx)		○L/L ○% ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Red Blood Cells (RBC)	☐		(xxxxx.xxxxx)		10^12/L M/mm3 Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		Yes No	Only required for results outside of normal range, may be left blank

Platelets	☐		(xxxxx.xxxxx)		○10^9/L ○K/mm3 ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

White Blood Cells (WBC)	☐		(xxxxx.xxxxx)		○ 10^9/L ○ K/mm3 ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Coagulation Measures - Coag.

[Revision: Revision 2]

(Visit ID = 90 / Visit Display Name = Visit 3 (POD 4) / Visit Abbrev = V3-D4 / PageID = 30 / Page Display Name = Coagulation Measures - Coag. / Description = Labs - Coagulation - Coag. - Revision 2)

Coagulation		
* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

Please only record the last lab sample collected prior to surgery at this visit and record any other lab samples that were collected at this visit in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as a Medical History Entry

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Prothrombin Time (PT)	☐		(xxxxx.xxxxx)		○Seconds ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Activated Partial Thomboplasin Time (aPTT)	☐		(xxxxx.xxxxx)		○Seconds ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

INR	☐		(xxxxx.xxxxx)		○ Ratio ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Fibrinogen	☐		(xxxxx.xxxxx)		○ g/L ○ mg/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Coagulation Measures - ROTEM

[Revision: Revision 2]

(Visit ID = 90 / Visit Display Name = Visit 3 (POD 4) / Visit Abbrev = V3-D4 / PageID = 40 / Page Display Name = Coagulation Measures - ROTEM / Description = Labs - Coagulation - ROTEM - Revision 2)

ROTEM		
* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
ROTEM EXTEM CT	☐		(xxxxx.xxxxx)		○ Seconds ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

ROTEM EXTEM MCF	☐		(xxxxx.xxxxx)		○mm ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

ROTEM FIBTEM MCF	☐		(xxxxx.xxxxx)		○ mm ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Coagulation Measures - Platelets

[Revision: Revision 2]

(Visit ID = 90 / Visit Display Name = Visit 3 (POD 4) / Visit Abbrev = V3-D4 / PageID = 50 / Page Display Name = Coagulation Measures - Platelets / Description = Labs - Coagulation - Platelets - Revision 2)

Platelets		
* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Platelet Count	☐		(xxxxx.xxxxx)		○ µL ○ 10^9/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Platelet Function	☐		(xxxxx.xxxxx)		○mg/dL ○% ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Visit 3 (POD 5)

Clinical Chemistry

[Revision: Revision 2]

(Visit ID = 100 / Visit Display Name = Visit 3 (POD 5) / Visit Abbrev = V3-D5 / PageID = 10 / Page Display Name = Clinical Chemistry / Description = Labs - Clinical Chemistry - Revision 2)

* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

Please only record the last lab sample collected prior to surgery at this visit and record any other lab samples that were collected at this visit in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as a Medical History Entry

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Total Bilirubin	☐		(xxxxx.xxxxx)		○ µmol/L ○ mg/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Alanine Aminotransferase (ALT)	☐		(xxxxx.xxxxx)		○IU/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Alkaline Phosphatase (ALP) ☐		(xxxxx.xxxxx)		○IU/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Creatinine	☐		(xxxxx.xxxxx)		μmol/L mg/dL Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		Yes No	Only required for results outside of normal range, may be left blank

Troponin I-hs	☐		(xxxxx.xxxxx)		○ mmol/L ○ ng/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Troponin T-hs	☐		(xxxxx.xxxxx)		○mmol/L ○ng/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Sodium	☐		(xxxxx.xxxxx)		○ mmol/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Potassium	☐		(xxxxx.xxxxx)		○mmol/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Chloride	☐		(xxxxx.xxxxx)		○ mmol/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Bicarbonate	☐		(xxxxx.xxxxx)		○µmol/L ○mmol/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank
pH	☐		(xxxxx.xxxxx)		○None ○Other			○Yes ○No	Only required for results outside of normal range, may be left blank

Haematology (CBC)

[Revision: Revision 2]

(Visit ID = 100 / Visit Display Name = Visit 3 (POD 5) / Visit Abbrev = V3-D5 / PageID = 20 / Page Display Name = Haematology (CBC) / Description = Labs - Hematology - Revision 2)

* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

Please only record the last lab sample collected prior to surgery at this visit and record any other lab samples that were collected at this visit in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as a Medical History Entry

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Hemoglobin (HGB)	☐		(xxxxx.xxxxx)		○ g/L ○ g/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Hematocrit (HCT)	☐		(xxxxx.xxxxx)		○L/L ○% ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Red Blood Cells (RBC)	☐		(xxxxx.xxxxx)		10^12/L M/mm3 Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		Yes No	Only required for results outside of normal range, may be left blank

Platelets	☐		(xxxxx.xxxxx)		○10^9/L ○K/mm3 ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

White Blood Cells (WBC)	☐		(xxxxx.xxxxx)		○ 10^9/L ○ K/mm3 ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Coagulation Measures - Coag.

[Revision: Revision 2]

(Visit ID = 100 / Visit Display Name = Visit 3 (POD 5) / Visit Abbrev = V3-D5 / PageID = 30 / Page Display Name = Coagulation Measures - Coag. / Description = Labs - Coagulation - Coag. - Revision 2)

Coagulation		
* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

Please only record the last lab sample collected prior to surgery at this visit and record any other lab samples that were collected at this visit in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as a Medical History Entry

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Prothrombin Time (PT)	☐		(xxxxx.xxxxx)		○Seconds ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Activated Partial Thomboplasin Time (aPTT)	☐		(xxxxx.xxxxx)		○Seconds ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

INR	☐		(xxxxx.xxxxx)		○ Ratio ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Fibrinogen	☐		(xxxxx.xxxxx)		○ g/L ○ mg/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Coagulation Measures - ROTEM

[Revision: Revision 2]

(Visit ID = 100 / Visit Display Name = Visit 3 (POD 5) / Visit Abbrev = V3-D5 / PageID = 40 / Page Display Name = Coagulation Measures - ROTEM / Description = Labs - Coagulation - ROTEM - Revision 2)

ROTEM		
* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
ROTEM EXTEM CT	☐		(xxxxx.xxxxx)		○ Seconds ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

ROTEM EXTEM MCF	☐		(xxxxx.xxxxx)		○mm ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

ROTEM FIBTEM MCF	☐		(xxxxx.xxxxx)		○ mm ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Coagulation Measures - Platelets

[Revision: Revision 2]

(Visit ID = 100 / Visit Display Name = Visit 3 (POD 5) / Visit Abbrev = V3-D5 / PageID = 50 / Page Display Name = Coagulation Measures - Platelets / Description = Labs - Coagulation - Platelets - Revision 2)

Platelets		
* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Platelet Count	☐		(xxxxx.xxxxx)		○ µL ○ 10^9/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Platelet Function	☐		(xxxxx.xxxxx)		○mg/dL ○% ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Visit 3 (POD 6)

Clinical Chemistry

[Revision: Revision 2]

(Visit ID = 110 / Visit Display Name = Visit 3 (POD 6) / Visit Abbrev = V3-D6 / PageID = 10 / Page Display Name = Clinical Chemistry / Description = Labs - Clinical Chemistry - Revision 2)

* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

Please only record the last lab sample collected prior to surgery at this visit and record any other lab samples that were collected at this visit in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as a Medical History Entry

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Total Bilirubin	☐		(xxxxx.xxxxx)		○ µmol/L ○ mg/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Alanine Aminotransferase (ALT)	☐		(xxxxx.xxxxx)		○IU/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Alkaline Phosphatase (ALP) ☐		(xxxxx.xxxxx)		○IU/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Creatinine	☐		(xxxxx.xxxxx)		μmol/L mg/dL Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		Yes No	Only required for results outside of normal range, may be left blank

Troponin I-hs	☐		(xxxxx.xxxxx)		○mmol/L ○ng/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Troponin T-hs	☐		(xxxxx.xxxxx)		○mmol/L ○ng/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Sodium	☐		(xxxxx.xxxxx)		○mmol/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Potassium	☐		(xxxxx.xxxxx)		○mmol/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Chloride	☐		(xxxxx.xxxxx)		○ mmol/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Bicarbonate	☐		(xxxxx.xxxxx)		○µmol/L ○mmol/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank
pH	☐		(xxxxx.xxxxx)		○None ○Other			○Yes ○No	Only required for results outside of normal range, may be left blank

Haematology (CBC)

[Revision: Revision 2]

(Visit ID = 110 / Visit Display Name = Visit 3 (POD 6) / Visit Abbrev = V3-D6 / PageID = 20 / Page Display Name = Haematology (CBC) / Description = Labs - Hematology - Revision 2)

* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

Please only record the last lab sample collected prior to surgery at this visit and record any other lab samples that were collected at this visit in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as a Medical History Entry

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Hemoglobin (HGB)	☐		(xxxxx.xxxxx)		○ g/L ○ g/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Hematocrit (HCT)	☐		(xxxxx.xxxxx)		○L/L ○% ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Red Blood Cells (RBC)	☐		(xxxxx.xxxxx)		○ 10^12/L ○ M/mm3 ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Platelets	☐		(xxxxx.xxxxx)		○10^9/L ○K/mm3 ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

White Blood Cells (WBC)	☐		(xxxxx.xxxxx)		○ 10^9/L ○ K/mm3 ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Coagulation Measures - Coag.

[Revision: Revision 2]

(Visit ID = 110 / Visit Display Name = Visit 3 (POD 6) / Visit Abbrev = V3-D6 / PageID = 30 / Page Display Name = Coagulation Measures - Coag. / Description = Labs - Coagulation - Coag. - Revision 2)

Coagulation		
* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

Please only record the last lab sample collected prior to surgery at this visit and record any other lab samples that were collected at this visit in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as a Medical History Entry

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Prothrombin Time (PT)	☐		(xxxxx.xxxxx)		○Seconds ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Activated Partial Thomboplasin Time (aPTT)	☐		(xxxxx.xxxxx)		○Seconds ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

INR	☐		(xxxxx.xxxxx)		○ Ratio ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Fibrinogen	☐		(xxxxx.xxxxx)		○ g/L ○ mg/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Coagulation Measures - ROTEM

[Revision: Revision 2]

(Visit ID = 110 / Visit Display Name = Visit 3 (POD 6) / Visit Abbrev = V3-D6 / PageID = 40 / Page Display Name = Coagulation Measures - ROTEM / Description = Labs - Coagulation - ROTEM - Revision 2)

ROTEM		
* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
ROTEM EXTEM CT	☐		(xxxxx.xxxxx)		○Seconds ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

ROTEM EXTEM MCF	☐		(xxxxx.xxxxx)		○mm ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

ROTEM FIBTEM MCF	☐		(xxxxx.xxxxx)		○ mm ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Coagulation Measures - Platelets

[Revision: Revision 2]

(Visit ID = 110 / Visit Display Name = Visit 3 (POD 6) / Visit Abbrev = V3-D6 / PageID = 50 / Page Display Name = Coagulation Measures - Platelets / Description = Labs - Coagulation - Platelets - Revision 2)

Platelets		
* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Platelet Count	☐		(xxxxx.xxxxx)		○ µL ○ 10^9/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Platelet Function	☐		(xxxxx.xxxxx)		○mg/dL ○% ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Visit 3 (POD 7)

Clinical Chemistry

[Revision: Revision 2]

(Visit ID = 120 / Visit Display Name = Visit 3 (POD 7) / Visit Abbrev = V3-D7 / PageID = 10 / Page Display Name = Clinical Chemistry / Description = Labs - Clinical Chemistry - Revision 2)

* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

Please only record the last lab sample collected prior to surgery at this visit and record any other lab samples that were collected at this visit in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as a Medical History Entry

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Total Bilirubin	☐		(xxxxx.xxxxx)		○ µmol/L ○ mg/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Alanine Aminotransferase (ALT)	☐		(xxxxx.xxxxx)		○IU/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Alkaline Phosphatase (ALP) ☐		(xxxxx.xxxxx)		○IU/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Creatinine	☐		(xxxxx.xxxxx)		○ µmol/L ○ mg/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Troponin I-hs	☐		(xxxxx.xxxxx)		○ mmol/L ○ ng/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Troponin T-hs	☐		(xxxxx.xxxxx)		○ mmol/L ○ ng/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Sodium	☐		(xxxxx.xxxxx)		○mmol/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Potassium	☐		(xxxxx.xxxxx)		○mmol/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Chloride	☐		(xxxxx.xxxxx)		○mmol/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Bicarbonate	☐		(xxxxx.xxxxx)		○ µmol/L ○ mmol/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank
pH	☐		(xxxxx.xxxxx)		○ None ○ Other			○ Yes ○ No	Only required for results outside of normal range, may be left blank

Haematology (CBC)

[Revision: Revision 2]

(Visit ID = 120 / Visit Display Name = Visit 3 (POD 7) / Visit Abbrev = V3-D7 / PageID = 20 / Page Display Name = Haematology (CBC) / Description = Labs - Hematology - Revision 2)

* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

Please only record the last lab sample collected prior to surgery at this visit and record any other lab samples that were collected at this visit in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as a Medical History Entry

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Hemoglobin (HGB)	☐		(xxxxx.xxxxx)		○ g/L ○ g/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Hematocrit (HCT)	☐		(xxxxx.xxxxx)		○L/L ○% ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Red Blood Cells (RBC)	☐		(xxxxx.xxxxx)		10^12/L M/mm3 Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		Yes No	Only required for results outside of normal range, may be left blank

Platelets	☐		(xxxxx.xxxxx)		○10^9/L ○K/mm3 ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

White Blood Cells (WBC)	☐		(xxxxx.xxxxx)		○ 10^9/L ○ K/mm3 ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Coagulation Measures - Coag.

[Revision: Revision 2]

(Visit ID = 120 / Visit Display Name = Visit 3 (POD 7) / Visit Abbrev = V3-D7 / PageID = 30 / Page Display Name = Coagulation Measures - Coag. / Description = Labs - Coagulation - Coag. - Revision 2)

Coagulation		
* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

Please only record the last lab sample collected prior to surgery at this visit and record any other lab samples that were collected at this visit in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as a Medical History Entry

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Prothrombin Time (PT)	☐		(xxxxx.xxxxx)		○Seconds ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Activated Partial Thomboplasin Time (aPTT)	☐		(xxxxx.xxxxx)		○Seconds ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

INR	☐		(xxxxx.xxxxx)		○ Ratio ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Fibrinogen	☐		(xxxxx.xxxxx)		○ g/L ○ mg/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Coagulation Measures - ROTEM

[Revision: Revision 2]

(Visit ID = 120 / Visit Display Name = Visit 3 (POD 7) / Visit Abbrev = V3-D7 / PageID = 40 / Page Display Name = Coagulation Measures - ROTEM / Description = Labs - Coagulation - ROTEM - Revision 2)

ROTEM		
* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
ROTEM EXTEM CT	☐		(xxxxx.xxxxx)		○ Seconds ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

ROTEM EXTEM MCF	☐		(xxxxx.xxxxx)		○mm ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

ROTEM FIBTEM MCF	☐		(xxxxx.xxxxx)		○ mm ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Coagulation Measures - Platelets

[Revision: Revision 2]

(Visit ID = 120 / Visit Display Name = Visit 3 (POD 7) / Visit Abbrev = V3-D7 / PageID = 50 / Page Display Name = Coagulation Measures - Platelets / Description = Labs - Coagulation - Platelets - Revision 2)

Platelets		
* Was a sample collected?	○ Yes ○ No	
* If No, please specify the reason why the sample was not collected		

Please only record the last lab sample collected of the day at this visit and record any other lab samples that were collected prior to this one in the 'Additional Assessments' visit.

The lab results collected upon ICU Arrival must be recorded in the 'Additional Assessments' visit

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as an Adverse Event

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Platelet Count	☐		(xxxxx.xxxxx)		○ µL ○ 10^9/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Platelet Function	☐		(xxxxx.xxxxx)		○mg/dL ○% ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Visit 4

Additional Surgery

[Revision: Revision 2]

(Visit ID = 60 / Visit Display Name = Visit 4 / Visit Abbrev = V4 / PageID = 10 (*) / Page Display Name = Additional Surgery / Description = Surgery - Revision 2)

Surgical Procedure performed (check all that apply)	
ACB x	☐
* # of Coronaries	(format xx)
AV repair/replace	☐
MV repair/replace	☐
TV repair/replace	☐
PV repair/replace	☐
Myectomy	☐
ASD repair	☐
VSD repair	☐
LV Aneurysmectomy	☐
Complex Congenital	☐
Maze	☐
ECMO insertion	☐
IABP insertion	☐
LVAD/RVAD insertion	☐
Surgery on Aorta (check all that apply):	
Ascending	☐
Arch	☐
Descending	☐
Other	☐
* If Other, please specify	

Procedure Details		
* Reason for procedure	○ Surgical Re-exploration ○ Other	
* Cause of re-exploration	○ Bleeding ○ Tamponade ○ Other	
* If Other, please specify		
* Other reason for procedure		
* Surgical procedure performed		
* Urgency	○ Elective ○ Urgent ○ Emergency	
* Start date of surgery		(DD-MMM-YYYY)
* Start time of surgery		(HH24:MI)
End date of surgery is different to the start date of the surgery	☐	
* End date of surgery		(DD-MMM-YYYY)
* End time of surgery		(HH24:MI)
Dosing details		
Total heparin dose (U)		(format xxxxx.x)
Total protamine dose (mg)		(format xxxxx.x)
Please enter either Tranexamic acid dose or Aminocaproic acid dose below.		
Total tranexamic acid (TXA) dose (U)		(format xxxxx.x)
Total Aminocaproic acid dose		(format xxxxx.x)

Total Aminocaproic acid dose unit	○ g ○ mg ○ Other	
Unit, Other		
ACT: Pre heparin (sec)		(format xxxxx.x)
ACT: Post heparin (sec)		(format xxxxx.x)
ACT: Post protamine (sec)		(format xxxxx.x)
Cardiopulmonary Bypass		
* Did the patient undergo CPB during surgery?	○ Yes ○ No	
Start date of CPB is different to the start date of the surgery	☐	
* Initial start date of CPB		(DD-MMM-YYYY)
* Initial start time of CPB		(HH24:MI)
Final end date of CPB is different to the start date of the surgery	☐	
* Final end date of CPB		(DD-MMM-YYYY)
* Final end time of CPB		(HH24:MI)
* CPB duration (minutes)		(format xxxxx.x)
* CPB Pump prime (mL)		(format xxxxx.x)
Fluid intake and output		
* Cell Salvage?	○ Yes ○ No	
* Blood collected (ml)		(format xxxxx.x)
* Blood returned (ml)		(format xxxxx.x)

Duration Details		
Cross clamp not applicable in this surgery	☐	
* Total Cross-clamp duration (minutes)		(format xxxxx.x)
Circulatory arrest not applicable in this surgery	☐	
* Circulatory arrest duration (minutes)		(format xxxxx.x)
Intubation/Extubation		
Intubation/Extubation not applicable in this surgery	☐	
Intubation date is different to the start date of the surgery	☐	
* Intubation Date		(DD-MMM-YYYY)
* Intubation Time		(HH24:MI)
Extubation date is different to the start date of the surgery	☐	
* Extubation Date		(DD-MMM-YYYY)
* Extubation Time		(HH24:MI)
Total intubation duration (minutes)	(auto calculated)	(format xxxx)

Hospital Admission - Initial

[Revision: Revision 2]

(Visit ID = 60 / Visit Display Name = Visit 4 / Visit Abbrev = V4 / PageID = 50 / Page Display Name = Hospital Admission - Initial / Description = Hospital Admissions - Revision 2)

Please ensure that any hospital admissions recorded on these pages are only recorded if the patient has been re-admitted after initial admission.

Please ensure that the hospital admission data recorded on this page is only for admission for the patients initial surgery. Any further re-admissions should be captured on the re-admissions page at this visit.

* Reason for Re-admission	○ Surgical Re-exploration ○ Other	
* If Other, please specify		
* Admission Date		(DD-MMM-YYYY)
* Admission Time		(HH24:MI)
* Discharge Date		(DD-MMM-YYYY)
* Discharge Time		(HH24:MI)

Intensive Care Unit (ICU) Duration

* Patient spent time in the ICU during this hospital stay?	○ Yes ○ No	
ICU start date is different to the Admission Date	☐	
* ICU Start Date		(DD-MMM-YYYY)
* ICU Start Time		(HH24:MI)
ICU end date is different to the ICU Start Date	☐	
* ICU End Date		(DD-MMM-YYYY)
* ICU End Time		(HH24:MI)

Total duration patient was in ICU (minutes)	(auto calculated)	(format xxxx)
Disposition to Rehab		
* Was patient admitted to rehab after hospital stay?	○ Yes ○ No	
* Rehab Admission Date		(DD-MMM-YYYY)
* Rehab Admission Time		(HH24:MI)
Rehab Discharge date is different to the Rehab Admission date	☐	
* Rehab Discharge Date		(DD-MMM-YYYY)
* Rehab Discharge Time		(HH24:MI)

Hospital Re-admissions

[Revision: Revision 2]

(Visit ID = 60 / Visit Display Name = Visit 4 / Visit Abbrev = V4 / PageID = 20 (*) / Page Display Name = Hospital Re-admissions / Description = Hospital Admissions - Revision 2)

Please ensure that any hospital admissions recorded on these pages are only recorded if the patient has been re-admitted after initial admission.

Please ensure that the hospital admission data recorded on this page is only for admission for the patients initial surgery. Any further re-admissions should be captured on the re-admissions page at this visit.

* Reason for Re-admission	○ Surgical Re-exploration ○ Other	
* If Other, please specify		
* Admission Date		(DD-MMM-YYYY)
* Admission Time		(HH24:MI)
* Discharge Date		(DD-MMM-YYYY)
* Discharge Time		(HH24:MI)

Intensive Care Unit (ICU) Duration

* Patient spent time in the ICU during this hospital stay?	○ Yes ○ No	
ICU start date is different to the Admission Date	☐	
* ICU Start Date		(DD-MMM-YYYY)
* ICU Start Time		(HH24:MI)
ICU end date is different to the ICU Start Date	☐	
* ICU End Date		(DD-MMM-YYYY)
* ICU End Time		(HH24:MI)

Total duration patient was in ICU (minutes)	(auto calculated)	(format xxxx)
Disposition to Rehab		
* Was patient admitted to rehab after hospital stay?	○ Yes ○ No	
* Rehab Admission Date		(DD-MMM-YYYY)
* Rehab Admission Time		(HH24:MI)
Rehab Discharge date is different to the Rehab Admission date	☐	
* Rehab Discharge Date		(DD-MMM-YYYY)
* Rehab Discharge Time		(HH24:MI)

Patient Survival

[Revision: Revision 2]

(Visit ID = 60 / Visit Display Name = Visit 4 / Visit Abbrev = V4 / PageID = 30 / Page Display Name = Patient Survival / Description = Patient Survival)

* Did patient complete study as per protocol?	○ Yes ○ No	
* Primary reason for discontinuation	○ Withdrawal of consent ○ Major protocol violation ○ Investigator's or Sponsor's decision ○ Adverse Event ○ Other	
Please ensure that the AE that resulted in study termination is linked to this page using the 'Page Links' functionality in the bottom left of the window		
* Please provide details		
* Date of completion/discontinuation		(DD-MMM-YYYY)
* Was study-blind broken at any point throughout the study?	○ Yes ○ No	
* If Yes, was study-blind intentionally broken because treatment information was required?	○ Yes ○ No	
* Please provide any additional details as to why study-blind was broken		
* Patient Outcome	○ Discharged from hospital ○ Still in hospital ○ Dead ○ Other	

* Date of Death		(DD-MMM-YYYY)
Time of Death (if known)		(HH24:MI)
* Please specify		

Patient Mortality

[Revision: Revision 2]

(Visit ID = 60 / Visit Display Name = Visit 4 / Visit Abbrev = V4 / PageID = 40 / Page Display Name = Patient Mortality / Description = Patient Mortality)

Date of Death (remote value)

Privacy Note: Please do not enter any personal health information, such as patient's spouses, relatives, physicians or hospitals name.

Please provide all available information about patient's death

Please use the page link functionality to link this page to the AE that resulted in the patient's death.

Events

Adverse Events

[Revision: Revision 2]

(Visit ID = 70 / Visit Display Name = Events / Visit Abbrev = EVENTS / PageID = 10 (*) / Page Display Name = Adverse Events / Description = Adverse Events)

* Adverse Event Term		
* Start Date		(UNK-UNK-UNK)
Please tick here if Start time is unknown	☐	
Start Time		(HH24:MI)
* Is condition ongoing?	○ Yes ○ No	
* Stop Date		(UNK-UNK-UNK)
Please tick here if Stop Time is unknown	☐	
Stop Time		(HH24:MI)
* Severity	○ Mild ○ Moderate ○ Severe	
* Relationship to IMP	○ Probable ○ Possible ○ Unlikely ○ Not related (unrelated) ○ Unclassified	
Description		

* IMP-related action taken	○ None ○ Product withdrawn ○ Dose reduced ○ Dose increased
* General action taken	○ None ○ Transfusion ○ Medication or other therapy started ○ Test performed ○ Other

Please ensure details of transfusion are recorded on a transfusions page and that the page link functionality is used to link these two pages together

If Adverse Event is considered serious, please ensure details of medications are recorded on a Concomitant Medications page and that the page link functionality is used to link these two pages together

* If Other, please specify

* Outcome	○ Recovered, resolved ○ Recovering, resolving ○ Not recovered, not resolved ○ Recovered, recovered with sequelae ○ Fatal ○ Unknown
* Is this event "serious"?	○ Yes ○ No

SAE Criteria (check all that apply)	
Results in death	☐
Is life-threatening	☐
Requires hospitalisation or prolongation of existing hospitalisation	☐

Results in persistent or significant disability/incapacity	☐
Is a congenital anomaly/birth defect	☐
Is another important medical event	☐

Concomitant Medications

[Revision: Revision 2]

(Visit ID = 70 / Visit Display Name = Events / Visit Abbrev = EVENTS / PageID = 20 (*) / Page Display Name = Concomitant Medications / Description = Preoperative, Intraoperative and Concomitant Medications)

Please record all concomitant medications taken by the patient here including medications that were taken during the patients surgery (including Inotropes and Vasopressors) as well as any medications that were taken up to 30 days prior to the patients surgery

* Medication name		
* Type of Medication	○ Concomitant Medication ○ Preoperative Medication ○ Intraoperative Medication ○ Other	
* If Other, please specify		
* Start Date		(UNK-UNK-UNK)
* Is medication ongoing?	○ Yes ○ No	
* Stop Date		(UNK-UNK-UNK)
* Indication		
* Dose per use		(format xxxxxxxx.xx)

* Unit	○ mg ○ g ○ µg ○ mL ○ IU ○ Sprays ○ Inhalations ○ Tablets ○ Other
* If Other, please specify	
* Route of administration	○ Oral ○ Sublingual ○ Inhalation ○ Topical ○ Subcutaneous ○ Intramuscular ○ Intravenous ○ Transdermal ○ Intraocular ○ Other
* If Other, please specify	

* Frequency of use	○ PRN - as needed ○ QAM - once in the morning ○ QHS - once in the evening ○ QD - once daily ○ BID - twice daily ○ TID - three times daily ○ QID - four times daily ○ QOD - every other day ○ QIW - once per week ○ Intravenously/continuously ○ Unknown ○ Other
* If Other, please specify	

Additional Assessments

Clinical Chemistry

[Revision: Revision 2]

(Visit ID = 130 / Visit Display Name = Additional Assessments / Visit Abbrev = ADD / PageID = 10 (*) / Page Display Name = Clinical Chemistry / Description = Labs - Clinical Chemistry - (repeating) - Revision 2)

Only lab samples that have not already been recorded elsewhere in the CRF should be recorded here.

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as a Medical History Entry if it occurred prior to initial surgery or as an Adverse Event if it occurred after initial surgery.

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Total Bilirubin	☐		(xxxxx.xxxxx)		○ µmol/L ○ mg/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Alanine Aminotransferase (ALT)	☐		(xxxxx.xxxxx)		○IU/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Alkaline Phosphatase (ALP)	☐		(xxxxx.xxxxx)		○ IU/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Creatinine	☐		(xxxxx.xxxxx)		○ µmol/L ○ mg/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Troponin I-hs	☐		(xxxxx.xxxxx)		○ mmol/L ○ ng/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Troponin T-hs	☐		(xxxxx.xxxxx)		○mmol/L ○ng/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Sodium	☐		(xxxxx.xxxxx)		○mmol/L ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Potassium	☐		(xxxxx.xxxxx)		○ mmol/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Chloride	☐		(xxxxx.xxxxx)		○ mmol/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Bicarbonate	☐		(xxxxx.xxxxx)		○ µmol/L ○ mmol/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank
pH	☐		(xxxxx.xxxxx)		○ None ○ Other			○ Yes ○ No	Only required for results outside of normal range, may be left blank

Haematology (CBC)

[Revision: Revision 2]

(Visit ID = 130 / Visit Display Name = Additional Assessments / Visit Abbrev = ADD / PageID = 20 (*) / Page Display Name = Haematology (CBC) / Description = Labs - Haematology (repeating) - Revision 2)

Only lab samples that have not already been recorded elsewhere in the CRF should be recorded here.

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as a Medical History Entry if it occurred prior to initial surgery or as an Adverse Event if it occurred after initial surgery.

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Hemoglobin (HGB)	☐		(xxxxx.xxxxx)		○ g/L ○ g/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Hematocrit (HCT)	☐		(xxxxx.xxxxx)		○L/L ○% ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Red Blood Cells (RBC)	☐		(xxxxx.xxxxx)		○ 10^12/L ○ M/mm3 ○ Other	10^6/µL is equivalent to M/mm3. If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Platelets	☐		(xxxxx.xxxxx)		○10^9/L ○K/mm3 ○Other	10^3/µL is equivalent to K/mm3. If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

White Blood Cells (WBC)	☐		(xxxxx.xxxxx)		○ 10^9/L ○ K/mm3 ○ Other	10^3/µL is equivalent to K/mm3. If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Coagulation Measures - Coag.

[Revision: Revision 2]

(Visit ID = 130 / Visit Display Name = Additional Assessments / Visit Abbrev = ADD / PageID = 30 (*) / Page Display Name = Coagulation Measures - Coag. / Description = Labs - Coagulation - Coag. (repeating) - Revision 2)

Coagulation

Only lab samples that have not already been recorded elsewhere in the CRF should be recorded here.

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as a Medical History Entry if it occurred prior to initial surgery or as an Adverse Event if it occurred after initial surgery.

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Prothrombin Time (PT)	☐		(xxxxx.xxxxx)		○Seconds ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

Activated Partial Thomboplasin Time (aPTT)	☐		(xxxxx.xxxxx)		○Seconds ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

INR	☐		(xxxxx.xxxxx)		○ Ratio ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Fibrinogen	☐		(xxxxx.xxxxx)		○ g/L ○ mg/dL ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Coagulation Measures - ROTEM

[Revision: Revision 2]

(Visit ID = 130 / Visit Display Name = Additional Assessments / Visit Abbrev = ADD / PageID = 40 (*) / Page Display Name = Coagulation Measures - ROTEM / Description = Labs - Coagulation - ROTEM)

ROTEM

Only lab samples that have not already been recorded elsewhere in the CRF should be recorded here.

* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as a Medical History Entry if it occurred prior to initial surgery or as an Adverse Event if it occurred after initial surgery.

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
ROTEM EXTEM CT	☐		(xxxxx.xxxxx)		○Seconds ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

ROTEM EXTEM MCF	☐		(xxxxx.xxxxx)		○mm ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank

ROTEM FIBTEM MCF	☐		(xxxxx.xxxxx)		○ mm ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Coagulation Measures - Platelets

[Revision: Revision 2]

(Visit ID = 130 / Visit Display Name = Additional Assessments / Visit Abbrev = ADD / PageID = 50 (*) / Page Display Name = Coagulation Measures - Platelets / Description = Labs - Coagulation - Platelets)

Platelets		
Only lab samples that have not already been recorded elsewhere in the CRF should be recorded here.		
* Collection Date		(DD-MMM-YYYY)
* Collection Time		(HH24:MI)
* Local Lab Name	(Lab Selection)	If the name of the local lab being used is not present please contact your CRA and/or Ergomed data management for assistance

Enter all results below

Result should be entered in the column "Result (numeric)" unless a numeric result is not available (e.g. "3-5" or "<2"), in which case enter results in non-numeric column

Any results considered CS (Clinically Significant) should be recorded as a Medical History Entry if it occurred prior to initial surgery or as an Adverse Event if it occurred after initial surgery.

Parameter	Check if not done	Result (numeric)		Result (non-numeric)	Unit		Unit, other	If out of normal range, was the result clinically significant?	
Platelet Count	☐		(xxxxx.xxxxx)		○ µL ○ 10^9/L ○ Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○ Yes ○ No	Only required for results outside of normal range, may be left blank

Platelet Function	☐		(xxxxx.xxxxx)		○mg/dL ○% ○Other	If an exact match is not available please select an equivalent. If an equivalent is not available please select 'Other' and enter the unit manually. Conversion of results to different units is not required.		○Yes ○No	Only required for results outside of normal range, may be left blank