Supplement 1 - EFACCT research professional study consensus statements

Q1	Follow-up Definition	Median	Consensus % Level
1.4	NIHR/Nationally Agreed Definition of Follow -Up: A nationally agreed definition of the term 'follow-up' and/or types of 'follow-up' in relation to research delivery in the NHS should be published by the NIHR so that all clinical research professionals, allied professions and associated bodies conform to a standard terminology and parameters.	Strongly Agree (7)	92%
Q2	**Barriers & Burdens**	**Median**	**Consensus % Level**
2.19	Trial sites are under constant pressure to open trials with expectations to recruit high numbers of trial participants to increasingly complex and higher intensity trials treating patients with rare cancers whilst being faced with reduced resources. Budgetary constraints and outdated payment terms which do not accurately reflect the requirements, time and effort of sites, represent a high risk to NHS organisations where audited and reduce the capacity to maintain effective trial delivery and meet patient needs through inadequate staffing levels. The NIHR needs to acknowledge the increased complexity of cancer trials, the workload impact in co-ordination and management, augmented lab work & data management demands and comprehend the nature of academic and commercial trials and their associated pressures on research delivery sites and staff through the development of an effective and consistently validated funding & support model.	Strongly Agree (7)	92%
2.35	The management of patient follow-up in cancer studies is a key factor affecting site capacity and ability to implement, recruit to and deliver effective research. Follow-up visits for cancer patients and research studies can continue for many years and often until death. Patients may also transfer from other hospitals for follow-up care, which has an impact on the research staff and capacity at site. Follow-up data is essential to the outcomes of research studies but the NIHR research delivery model focuses on and supports recruitment but not follow-up activities. With continual pressure to open studies to gain accruals the ability of teams to manage existing numbers of patients in follow-up is compromised leading to missed timelines, patient visits and missing data, which could be extremely detrimental to follow-up studies and invalidate results of the trial. These burdens and issues are not recognised within research delivery.	Strongly Agree (7)	88.00%
2.13	Principal Investigator oversight and involvement is lacking at times in certain tumour sites, studies or hospital locations, particularly for multi-site trusts where the PI works from one centre, leaving Research Nurses feeling unsupported. When new studies are set up it is important to ensure there is a clear understanding of roles and responsibilities of the research team so that workloads can be accurately assessed. Principal Investigators should be aware that they could delegate tasks according to GCP but retain overall responsibility for the study beyond the treatment elements and need to maintain involvement in patient follow-up and review.	Strongly Agree (7)	88.00%
2.4	Support and retention of research professionals, nurses and specialist roles as well as the provision of sufficiently skilled resource should be the focus of the NIHR and Trusts to ensure safe and efficient research environments and reduce excessive workloads. Staff turnover, changes, sickness and absence all have a significant impact on research implementation and delivery at sites.	Strongly Agree (7)	84.00%
2.23	Protocols and study documentation supplied to assess capacity and capability do not show the impact of eCRFs or the full extent of information and demographic data required. High data demands and the management of sponsor data queries are a significant and time-consuming administrative burden for sites. Difficulties in communication or slow responses can lead to extended or additional work for sites especially where a sponsor's representative does not comprehend the problems in obtaining retrospective information or understand the nature of certain data issues.	Strongly Agree (7)	84.00%
2.22	Clinical Research Organisations tend to outsource a lot of work which adds to a site's administrative burden and complexity in having to deal with multiple supplier IT platforms and electronic data capture systems (e.g. RTSM, EDC, eCRFs, ePRO & eQoL), all with different user logins and interfaces. The complexities of some systems can require significant time to train which is difficult to include into the busy schedules of teams and represents a further burden to sites.	Strongly Agree (7)	84.00%
2.29	Protocol defined timelines within some trials can be difficult for sites to achieve. Requirements for additional tests at trial entry or specific time points, such as CT scans, ECHOs, ECGs, can be challenging to co-ordinate due to resource issues, limited appointment availability or the length of time taken to receive some results e.g. blood results from pathology or slow reporting of scans from the imaging team.	Strongly Agree (7)	84.00%
2.11	Lack of organisational support to promote and raise the profile of clinical research impacts delivery at multiple levels. Patients may not be aware of the trials running within the organisation limiting their ability to participate or Trust staff/allied clinical professionals who are not research active may be resistant to getting involved or have limited capacity. If research is not part of everyday care and isn't promoted at a Trust, it can be deemed as being an additional element, not a routine choice or less important than other aspects of patient care. Trusts should support the involvement of all staff in research through providing training and/or incentives, in order to change perceptions, raise awareness, increase capacity and enhance collaboration between departments for the benefit of patients and the whole organisation.	Strongly Agree (7)	84.00%

2.36	Protocol amendments can lead to a large additional workload for sites and unplanned resource and capacity burdens. Amendments are becoming increasingly frequent with significant paperwork and administration, sometimes involving only minor changes or lacking clarity on changes. Some sponsors can introduce an entirely new study element via an amendment, which can be hard for sites to decline. Data collection goals are being changed with additional data points added to forms and an expectation for sites to collect this data retrospectively, which is frustrating and time consuming for sites. The additional time to train all delegated staff is a huge problem in a large system and can redirect resource from patient care and treatment to manage the paperwork for amendments on existing trials.	Strongly Agree (7)	80.00%
2.8	The process of study set up and approval continues to be slow for multiple reasons, but both overall effectiveness of trial implementation and delivery is affected by insufficient resources for administration, data management and the capacity of Finance Business Partners or co-coordinators, compounded by increasing levels of paperwork and administrative burden.	Strongly Agree (7)	80.00%
2.12	A lack of communication and collaboration between hospital departments, shared care organisations or clinical and non-clinical staff impacts effective research delivery with differing issues and priorities making treatments, interventions or training difficult to implement alongside a lack of understanding of the importance of clinical research, Good Clinical Practice and medical staff not having time to complete relevant training. Research teams can find negotiating time, interest and support of research challenging and exhausting when facing organisational resistance and negativity. When research is viewed in a negative way or is unsupported, it can be demoralising for teams and impede the skills development and confidence of new staff as well as being a significant barrier to efficient research.	Strongly Agree (7)	80.00%
2.32	Clinical pharmacokinetic (PK) studies are becoming increasingly complex with lengthy PK sampling or collection times falling outside of current available clinic hours.	Strongly Agree (7)	80.00%
2.30	Cancer research studies can be incredibly complex to deliver with targeted treatments being developed for patients in rare disease groups. Protocol designs are being developed with increasingly high data demands and additional tests, providing supplementary information rather than focused data to answer the research question. The addition of baseline visits between screening and initial treatment visit, requirement for central tissue testing, supply of archival tissue or additional biopsies can be time consuming and challenging for sites to deliver and some sites have limited ability to provide accurate RECIST reporting within the clinical trial timelines.	Strongly Agree (7)	80.00%
2.3	Due to a lack of research nurses and associated professionals too many trials are being managed by individual staff with research nurses often supporting more than one clinical area e.g. haematology & lung, and within those areas possibly recruiting to 15 or more studies. When managing a large number of studies it is very difficult to truly know all protocols well. Managing high study volumes is challenging particularly as trials are becoming more complex in nature, which limits the capacity of the research team to recruit and follow up patients.	Strongly Agree (7)	80.00%
2.44	The lack of IT integration in the NHS is a barrier to efficient trial delivery and data management due to stand alone IT systems, multiple incompatible databases, software providers and imaging systems requiring multiple log ins, and the need for data duplication, re-entry and cross checking causing additional workloads and data queries.	Strongly Agree (7)	80.00%
2.6	Insufficient levels of adequately trained resources can lead to staff feeling pressured to take on additional tasks that do not normally come under their remit, especially in set up, and a lack of clarity or merging of roles and responsibilities places additional burdens on team members. Where there are gaps in certain roles, such as no CNS in a particular speciality, research nurses may feel they need to step in to support a patient, despite their own limited capacity. The full involvement of research nurses in study set up, to ensure accurate assessment of capacity and capability, is time consuming, slow and challenging when trying to balance their clinical commitments, patient follow-up and recruitment to existing studies.	Strongly Agree (7)	80.00%
2.2	Trusts believe they can run complex cancer studies but with NHS resources currently stretched and a lack of resource allocation from research networks the capacity to support and maintain effective cancer clinical trial delivery, ensuring patient safety and needs are met is being impacted. Limited infrastructure and staff shortages mean supporting departments such as wards, clinics, radiology, pathology, pharmacy and various medical specialities, are struggling to accommodate additional trial workloads in a timely fashion and too many trials are being managed by individual research staff. Research trial delivery is one of the first areas to be reduced or impacted where a Trust or a department, such as pharmacy, has capacity issues.	Strongly Agree (7)	80.00%
2.1	There is a lack of understanding across the NIHR, Sponsors, LCRN's, Trusts and senior management of the complexities and workload in conducting cancer research, for example complex haematology trials, which has led to unrealistic expectations and enormous pressures on research teams at NHS sites.	Strongly Agree (7)	80.00%
2.28	Niche trial designs with narrow inclusion and exclusion criteria or those with very short screening periods (7 days for some activities) can be challenging for sites in meeting the required timelines and a barrier to recruitment.	Strongly Agree (7)	76.00%
2.41	Difficulties exist due to limited space in clinics or lack of suitable rooms to offer patients the required privacy and sufficient time to explain trials in a comfortable environment without being disturbed, or to take their bloods and conduct other investigations as needed.	Strongly Agree (7)	72.00%

2.27	Barriers to effective trial delivery occur where protocols are not user friendly or have been badly written, where healthcare systems, research professionals or patients have not been consulted during the design stage. A lack of respect for the experiences and knowledge of research delivery staff and patients through failure to involve them in helping design better protocols, CRFs and other study documentation can lead to fundamental design issues, generate data queries, impact efficient trial delivery and add significant burdens for participating sites and patients.	Strongly Agree (7)	72.00%
Q3	Analysis of Complexity	Median	Consensus % Level
3.21	Cancer clinical trial protocols have varying degrees of complexity but the burden of protocol procedures is growing which adds to the complexity of implementing and delivering studies, with incremental levels of training (e.g. 450 training slides on a 5 arm study with strict guidelines) and increased volumes of tests, questionnaires, visits, assessments and more detailed data requirements.	Strongly Agree (7)	96.00%
3.1	Cancer is no longer one diagnosis but a complex range of conditions with many sub-groups. Cancer clinical research complexity is growing as trials now study a wide range of cancers, rare tumours, haematological malignancies and molecular sub-types with treatments becoming precise, targeted and having more options at each stage of the cancer journey. Trials may now only be suitable for a subgroup of the cancer population, such as lymphoma, which has more than 70 sub-types. Sites need to have a greater number of trials open to ensure patients have the opportunity to participate, but each trial will recruit a smaller number of patients adding to the complexity of delivering research.	Strongly Agree (7)	92.00%
3.17	Managing the communication and co-ordination of clinical trial appointments, procedures, and diagnostics, e.g. mammography, ECHO, ECGs, clip insertion, CT scans, bone marrow & surgical/specialist procedures is pressurised and complicated when liaising with multi-disciplinary teams and support services to meet protocol specific timeframes or treatment windows. Aligning a study with the two-week wait or fitting it into a surgical pathway isn't always possible due to operational problems and capacity issues.	Strongly Agree (7)	88.00%
3.6	The clinical trial phase is a key determinant in study complexity with earlier phase studies typically more complex, requiring lots of visits, extra tests or PK analysis. Early phase clinical trials frequently need input from other departments e.g. ophthalmology or dermatology requiring collaboration to arrange time and appointments. Studies involving overnight stays can be hard to organise due to bed and resource capacity. Admitting patients for trial monitoring can be hard to justify and negotiate when beds are full. Later stage studies such as Phase 3 may include standard of care but complexity is added due to the larger volume of patients required and lengthy follow-up.	Strongly Agree (7)	88.00%
3.16	Protocol designs that involve short timelines and windows for procedures are more complex and logistically challenging for sites to deliver when trying to schedule registration, randomisation, assessments and treatment around the availability of NHS resources, especially where there is little flexibility from the sponsor. It can be difficult when a patient is excluded from a trial because of scan timings or initial bloods not having been taken by other clinicians who saw the patient first at diagnosis, but not as part of a trial. Additional complexities arise from late diagnostics where a patient comes to the centre late.	Strongly Agree (7)	80.00%
3.33	The management of Adverse Events, Serious Adverse Events and SUSARS can be time consuming in high risk trials or trials where there are a lot of these and can become complex if patients become very unwell. The cancer type, the nature of the patient population and how well they are will all significantly affect the complexity of the study and will affect the number of likely SAEs and amount of clinical input required.	Strongly Agree (7)	80.00%
3.25	Cancer clinical trial protocols are subject to more amendments than other specialities and are increasing in volume with complex studies having higher rates of amendments. These add to the complexity of delivering research, especially where there a multi-themed amendments, are perceived to get around guidelines or introduce new arms and additional IMPs (of the scale of a new study), likely due to the complexity of setting up several studies.	Strongly Agree (7)	76.00%
3.3	Complex trial designs make it difficult to cover the studies of colleagues who are on leave or absent and to maintain a team of skilled staff capable of delivering complex trials who are knowledgeable of patient pathways and treatment regimens. Consistent self-education and motivation is required of cancer research nurses and other research professionals to develop their knowledge to manage the complexities of new processes and treatments, keep ahead of the game, anticipate changes and maintain efficiency.	Strongly Agree (7)	76.00%
3.31	The relationship between a Research Nurse and a patient on cancer studies is important and can make a significant difference to the patient joining and remaining on a trial. Cancer patients have complex issues and needs, which increases the input from research staff. Research nurses/officers provide patients with information and support, deal with their questions and problems, arrange additional services (e.g. wheelchairs for appointments), keep track of admissions when a patient lives out of the geographical area of the recruiting site and more. Patient support on cancer studies can mean that research nurses have a CNS role, with patients approaching them first and bypassing their CNS. Complexity affects how research nurses can achieve efficiency in running a trial, within the constraints of their specific hospital or geographical location, whilst causing the least disruption to the patient given all their individual needs, such as the distance that the patients needs to drive and trying to keep visits to a minimum or support these over the phone.	Strongly Agree (7)	76.00%

3.19	There are complexities in managing logistical issues on studies, such as finding suitable locations for patient review or accessing services and facilities on a large site and where the treatment and laboratory areas are not near the oncology research office.	Strongly Agree (7)	72.00%
Q4	Factors Affecting Capacity	Median	Consensus % Level
4.2	Effective communication is the golden thread, which ensures an organisation can work effectively. The lack of integration, communication and collaboration across hospital sites and departments impacts trial delivery.	Strongly Agree (7)	88.00%
4.3	Inadequate staffing levels make it difficult for teams to meet the demands of current trials and to run as efficiently and effectively as possible.	Strongly Agree (7)	84.00%
4.45	Protocols, which are overly complicated, do not realistically work with hospital systems or have been written in such a way that they are hard to interpret impact capacity and efficiency. Studies with well-written protocols that consider the practicalities of trial delivery are much easier for sites to run.	Strongly Agree (7)	84.00%
4.46	The increasing complexity of new cancer trials and protocols can be challenging for sites to deliver and therefore detailed feasibility is essential, but the implications of running the study is not always apparent at the outset as frequent or unnecessary amendments can impact the capacity of the team as the study progresses.	Strongly Agree (7)	84.00%
4.8	Allied professional services and support departments such as radiology and pathology are crucial to the running of cancer clinical trials. It is essential that their involvement in trials is adequately rewarded financially and that professionals and teams are motivated by recognition of their scientific or academic contribution to research in trial publications.	Strongly Agree (7)	84.00%
4.6	Research support staff and data managers are essential to effective trial management and in supporting clinical teams through trial administration, laboratory work, quality assessments and data management, all of which are crucial in answering the clinical trial hypothesis. Ensuring there is continued funding in place to maintain their jobs is time consuming and challenging. Capacity is affected by the lack of data management and administrative resource available.	Strongly Agree (7)	80.00%
4.7	Workforce limitations of support departments involved in trial delivery e.g. radiology, pathology, cardiology etc. affects research capacity with some departments limited by resource and their ability to accommodate additional trial work in a timely manner.	Strongly Agree (7)	80.00%
4.1	NHS staffing constraints and reduced funding from the NIHR creates additional work for sites in trying to secure funding from different sources to support staffing or having to spread the attached workload from the reduced posts to existing staff.	Strongly Agree (7)	76.00%
Q5	Top Strategic Priorities	Median	Consensus % Level
5.13	Decision makers at national and local levels require a greater level of understanding of the constraints, resource and capacity issues and the priorities for research delivery and funding in the NHS.	Strongly Agree (7)	88.00%
5.2	Development of biomarkers for predicting suitability and response to treatment and early diagnosis techniques.	Strongly Agree (7)	88.00%
5.20	Promote cultural change and education to raise the profile of research and highlight the importance of clinical trials in the provision of cancer care within the NHS.	Strongly Agree (7)	88.00%
5.22	Ensure development of strong working relationships and rapport between research teams and supporting departments.	Strongly Agree (7)	88.00%
5.6	Improve collaboration and communication between Trusts and organisations (including non-NHS care providers such as hospices) to ensure patient care and choice is prioritised and all are given the opportunity to participate in research, where desired and appropriate.	Strongly Agree (7)	88.00%
5.12	The structure, activity and provision for research across the UK is variable and inconsistent. CRN funding needs to be reviewed to develop a clear equitable banding structure, which is measured and fairly reflects research activity.	Strongly Agree (7)	84.00%
5.19	Facilitate a detailed multi-disciplinary feasibility process to include all relevant staff and services ensuring all parties have capacity and capability to deliver all elements of the trial from the outset and can provide continued and consistent care during the treatment and follow-up stages.	Strongly Agree (7)	84.00%
5.28	Provide research specific induction training for registrars and consultants rotating hospitals to raise awareness of current trials and clinical research activities.	Strongly Agree (7)	84.00%
5.3	Investment in technology and the development of a national centralised database to enable access to trial information for researchers and patients with the ability to search by tumour site, patient factors and study eligibility in real time to expand trial opportunities to more patient groups.	Strongly Agree (7)	84.00%
5.31	Increase the use and uptake of IT systems, software and computer tablets for data capture and storage (e.g. eCRFs and electronic site files), support paper-light research and reduce or remove paper based data forms.	Strongly Agree (7)	84.00%

5.4	Increase accessibility, choice and participation in clinical trials to make a difference for patients in the NHS and to advance medicine, care, survival and access to the best evidence based treatments options.	Strongly Agree (7)	84.00%
5.7	Cancer research should be recognised as a speciality area with a core funding model developed to reflect the service and support requirements of research sites and meet the needs of patients within this complex field.	Strongly Agree (7)	84.00%
5.9	Improve data sharing between departments, hospitals and NHS care providers to facilitate accurate and timely data collection.	Strongly Agree (7)	84.00%
5.11	Increase external network funding for permanent, highly trained clinical trials staff in all NHS cancer centres and hospitals conducting cancer clinical research.	Strongly Agree (7)	80.00%
5.14	The current NIHR targets are unrealistic and frequently unachievable. More realistic objectives and targets should be developed to ensure patient safety, data integrity and trials can be practically delivered relative to the disease and protocol complexity.	Strongly Agree (7)	80.00%
5.15	A national costing review across the NHS organisation is required to price research effectively and agree standard costing templates ensuring Trusts accurately invoice for research activities and services provided.	Strongly Agree (7)	80.00%
5.24	Ensure MHRA inspections are conducted in a professional, collaborative and pragmatic manner working with R&D teams to limit onerous paperwork or the burden of overly bureaucratic procedures.	Strongly Agree (7)	80.00%
5.30	Prioritisation and implementation of a funding model recognising the workload and resource involvement in the provision of patient follow-up and quality data management.	Strongly Agree (7)	80.00%
5.1	Development of more targeted treatments to be able to offer trials to patients in all cancer areas and provide a balanced portfolio in each tumour group supported at local, regional and national levels.	Strongly Agree (7)	76.00%
5.16	Research sites need a way of assessing complexity to allocate resource, which is accurate, validated and future proofed.	Strongly Agree (7)	76.00%
5.18	Raise awareness of the importance of the continued support of Principal Investigators and Co-Investigators throughout a research study and ensure that they maintain oversight, active involvement and responsibility.	Strongly Agree (7)	76.00%
5.23	Develop strong and collaborative working relationships between site and sponsor staff.	Strongly Agree (7)	76.00%
5.32	Invest in staff training and development to include cancer specific modules so that research professionals are confident in discussing the disease and trial processes to patients.	Strongly Agree (7)	76.00%
Q6	Effective Research Practice	Median	Consensus % Level
6.17	Good communication skills and effective patient relationships help participants understand the trials and what participation will mean for them.	Strongly Agree (7)	88.00%
6.2	Well run, established departments and research teams who receive regular training, are efficient, proactive, flexible to change and demonstrate a wealth of knowledge and excellence in clinical trial delivery.	Strongly Agree (7)	84.00%
6.14	Principal Investigators who proactively support and engage with the research team, are available to provide advice when required, maintain oversight on their trials, including follow-up visits and discussion of treatment plans, ensure that trials are run effectively and safely in their research area.	Strongly Agree (7)	80.00%
6.18	Effective practice is demonstrated by dedicated staff who are willing to go above and beyond to recruit and support patients in clinical trials. Caring and skilled research professionals who treat patients as individuals and not just as a recruitment figure are appreciated by patients who value their support, and continue on the trial for follow-up visits and are less likely to withdraw from studies.	Strongly Agree (7)	80.00%
6.21	The provision of dedicated teams and specialists for specific cancer disease areas/sites within trial units enhances research delivery and staff knowledge in their speciality, in contrast to stretching resources across multiple specialisms.	Strongly Agree (7)	80.00%
6.24	The dedication, passion and skill of research staff and putting the patient's best interest first greatly contributes to the effective running of trials in the NHS, despite being understaffed, and strong collaborative teamwork supports staff retention under very tight circumstances.	Strongly Agree (7)	80.00%
6.25	Excellent communication and collaboration between supporting departments, clinics, staff roles and specialisms is demonstrated in effective research practice and will support efficient trial delivery.	Strongly Agree (7)	80.00%

6.23	Positive attitudes, open communication and respect across professions and roles, clear direction and guidance, sharing of best practices and the raising of concerns will support comprehension between all areas and parties involved in clinical research within the NHS and is essential to support future effective research delivery.	Strongly Agree (7)	76.00%
6.7	Patients are very positive about trial participation and really enjoy acknowledgement of their involvement. Feedback, communication, newsletters or publications through the media or from trial units demonstrates good practice.	Strongly Agree (7)	76.00%
Q7	Additional Delphi Considerations	Median	Consensus % Level
7.3	Supporting the primary end points of clinical trials should be the main goal of the NIHR and follow-up should be appropriately funded to achieve this.	Strongly Agree (7)	72.00%