CHALLENGES IN PAEDIATRIC CLINICAL RESEARCH DURING THE COVID-19 PANDEMIC

BASELINE DATA OF THE CANCER CLINICAL TRIAL UNIT BEFORE MARCH 2020

1. Phase I and II cancer clinical trials actively recruiting as of the 28th February 2020 (those that were interrupted previously for efficacy analysis and have not resumed are not included):

   SOLID TUMORS *[text]*:

   LEUKEMIA/LYMPHOMA *[text]*:

   MOLECULAR COLLABORATIVE NATIONAL/INTERNATIONAL PLATFORMS *[text]*:

2. Number of Phase I *[numeric]* and II *[numeric]* cancer clinical trials and molecular platforms in start-up phase as of the 28th February 2020 (from site selection confirmation to site initiation visit) not yet recruiting:
   a. Phase I *[numeric]*:
   b. Phase II *[numeric]:*
   c. Molecular platforms *[numeric]:*

3. Number of fully dedicated people working in your unit as of the 28th February 2020 (include each person in only one category):
   - Medical doctors *[numeric]*:
   - Nurses *[numeric]*:
   - Study Coordinators *[numeric]*:
   - Pharmacists *[numeric]*:
   - Data Managers *[numeric]:*
   - Project Managers *[numeric]*:
   - Statisticians *[numeric]*:
   - Biologists/Scientists *[numeric]*:
   - Secretaries *[numeric]*:
   - Other (Pharmacy assistant, etc) *[numeric]*:

4. Number of patients recruited in your unit in 2019 *[numeric]* in Phase I-II cancer trials and molecular platforms (Please in this section do not include patients that were only pre-screened [e.g. those in the afatinib study for which tumour was sent for *Erb* analysis and were not ultimately included in the trial]. If a patient participated in two or more trials or molecular platforms, this patient counts as many participations in them):

a. Number of Patients included in Phase I-II cancer trials:
b. Number of Patients included in molecular platforms:

QUESTIONNAIRE ABOUT THE ACTIVITY DURING THE MONTHS OF MARCH AND APRIL 2020

Impact on staff in March and April:

1. Has your unit suffered shortages of on-site staff? *[Yes/No]*
   If yes, please specify the number of people affected in each category of causes and include each person in only one category:
   a. Sick or potentially infected workers *[numeric]*:
   b. Institutional contingency policy (e.g. remote working mandatory) *[numeric]*:
   c. Workers sent to other areas according to health-policy organization *[numeric]*:
   d. Other *[please, specify] [numeric]*:
2. Has your unit managed to perform remote data entry? *[Yes/No]*
   If *yes*, did you have the appropriate means to have people working at home (e.g remote access to hospital software [Virtual private network])? *[Yes/No]*

Impact on on-site activities performed by the Sponsors in March and April:

1. Have you had to postpone any site activation visit in your unit? *[Yes/No]*
   a. If *yes*, how many planned site activation visits have been postponed in your unit and who took the decision to postpone it?
      i. Sponsor decision *[numeric]*:
      ii. Local PI decision *[numeric]*:
      iii. Institution decision *[numeric]*:
      iv. Combination/Other *[please, specify] [numeric]*:
2. Have you had to postpone any monitoring visit in your unit? *[Yes/No]*
   a. If *yes*, how many monitoring visits have been postponed in your unit and who took the decision to postpone it?
      i. Sponsor decision *[numeric]*:
      ii. Local PI decision *[numeric]*:
      iii. Institution decision *[numeric]*:
      iv. Combination/Other *[please, specify] [numeric]*:
3. Have there been any site activation or monitoring visits performed remotely? *[Yes/No]*

a. If *yes*, how many site activation visits have been performed remotely *[numeric]*?
b. If *yes*, how many monitoring visits have been performed remotely *[numeric]*?

4. Have there been any site activation or monitoring visits performed on-site? *[Yes/No]*
    c. If *yes*, how many site activation visits have been performed on-site *[numeric]*?
    d. If *yes*, how many monitoring visits have been performed on-site *[numeric]*?

Impact on recruitment in March and April (Applies only to those trials you included in the Baseline Section in page 2):

1. Have you managed to continue recruiting? *[Yes/No]*
2. How many patients have been recruited in this period *[numeric]*?
3. Please include all studies that have stopped recruitment for "COVID-19 related reasons" in this period (if a study was put on hold as per pre-planned safety/efficacy analysis other than COVID-19 please do not mark):
   SOLID TUMORS *[text]*:
   LEUKEMIA/LYMPHOMA *[text]*:
   MOLECULAR COLLABORATIVE NATIONAL/INTERNATIONAL PLATFORMS *[text]*:

Impact on patient care organization in March and April (Patient visits include safety visits, treatment visits, follow-up visits, etc):

1. Has your site suffered any kind of restriction to treat patients? *[Yes/No]*
2. Have you conducted on-site patient visits in your unit? *[Yes/No]*
3. Have you conducted patient visits that should have been conducted on site in other health care institutions closer to the patient's home? *[Yes/No]*
4. Have you conducted remote patient visits (e.g. by phone)? *[Yes/No]*
5. Have you rescheduled patient visits (e.g. moving dates, changing procedure, etc) in your unit? *[Yes/No]*
6. Have you cancelled patient visits in your unit? *[Yes/No]*

If it is possible, please provide the following information:

- How many patient visits have been conducted on site in your unit *[numeric]*?
- How many patient visits have been performed in other health care institutions closer to the patient's home *[numeric]*?
- How many patient visits have been conducted remotely (e.g. by phone) *[numeric]*?

- How many patient visits have been rescheduled in your unit *[numeric]*?
- How many patient visits have been cancelled in your unit *[numeric]*?

7. Have there been patients that have suffered treatment delays in your unit? *[Yes/No]*

   If *yes*, please specify the number and the main reason for each patient delay:

   a. Not possible to ensure drug supply *[numeric]*:
   b. Not possible to ensure patient's safety *[numeric]*:
   c. Patient/parents' decision *[numeric]*:
   d. Other *[please, specify] [numeric]*:

8. Have there been patients that have suffered treatment discontinuations in your unit? *[Yes/No]*

   If *yes*, please specify the number and the main reason for each patient delay:

   a. Not possible to ensure drug supply *[numeric]*:
   b. Not possible to ensure patient's safety *[numeric]*:
   c. Patient/parents' decision *[numeric]*:
   d. Other *[please, specify] [numeric]*:

9. Has your unit suffered any kind of restriction to perform trials assessments (e.g. blood puncture or sedation procedures) due to local infection prevention strategy? *[Yes/No]*
10. How many patients could not be recruited into a trial among candidates in your unit *[numeric]* for COVID-19 related issues?
11. In case participation in clinical trials has not been possible, please specify the number of patients and the decision taken for those patients:

    a. No treatment *[numeric]*:
    b. Other treatment out of trial *[numeric]*:
    c. Inclusion on trial in another site *[numeric]*:
    d. Other *[please, specify] [numeric]*:

Impact on medicinal products and research tools/devices in March and April:

1. Has your unit suffered shortages of investigational medications? *[Yes/No]*

   If yes, for how many trials *[numeric]*?

2. Has your unit managed to ship investigational medications to the patient's home or to local healthcare centres to avoid hospital visits? *[Yes/No]*

   If yes, for how many trials *[numeric]*?

   Did the sponsor facilitate shipment of the investigational product? *[Yes/No]*

3. Has your unit managed to provide increased drug supplies to patients to avoid repeated visits to hospital? *[Yes/No]*
   If yes, for how many trials *[numeric]*?
4. In case you had to refer patients to other institutions in order to avoid long-distance travel, was the Sponsor in agreement beforehand? *[Yes/No]*
5. Has your unit suffered shortages or delays in the reception of investigational support tools such as kits or devices? *[Yes/No]*
   If yes, which shortages has your unit suffered *[free text]* and for how many clinical trials *[numeric]*?
6. Have there been any difficulties to send research samples from your unit? *[Yes/No]*

Impact on regulatory/legal aspects in March and April:

1. Have pending contracts with sponsors been impacted by the pandemic? *[Yes/No]*
   If *yes*, please specify the number (if known) *[numeric]* and in which manner (e.g. contracts have been postponed, revision of budget has been delayed, etc) *[free text]*?
2. Has your unit been provided with contingency plans by sponsors with recommendations for their trials or for supporting or recording of data related to COVID-19 infections? *[Yes/No]*
   If *yes*, how many sponsors have approached your unit?
3. Has your unit created specific contingency plans for the management of issues related to the COVID-19 crisis? *[Yes/No]*
4. Has your National Regulatory Authority created specific contingency plans for the management of issues related to the COVID-19 crisis? *[Yes/No]*

Future perspectives:

1. How do you think this crisis will impact your unit recruitment rates until the end of the year compared to 2019? Select one of the following:
   a. The recruitment will be lower ☐
   b. The recruitment will be similar ☐
   c. The recruitment will be higher ☐

2. Are you planning any change in your unit organization for the next months (e.g. to promote home-working, promote remote monitoring visits or SIVs, etc? *[Yes/No].* If *yes*, please explain further *(free text)*

3. Do you think that this crisis will make you be better prepared for potential future health emergencies? *[Yes/No]*
4. Any other comments (e.g. Any positive effect of the COVID-19 pandemic for the future, main concerns, worries, etc): *[free text]*