ITCC Clinical Fellowship description

The training program in the Princess Maxima Center for pediatric oncology is based on the model of 'learning by doing'. Fellows will participate in all steps of the patient's journey across phase I-II clinical trials and in the development and writing of clinical trials. In addition to the practical aspects, fellows will be provided with learning material covering the following sections (e.g. regulatory, ethical, etc) and will be encouraged to participate in relevant meetings and training sessions/courses that will complement their learning process.

1. Clinical experience

The clinical activity of the Princess Maxima is divided in three departments: Hemato-oncology (HO), solid tumors and brain tumors. Collectively, around 700 patients per year are attended in the three departments, begin the HO the largest one with 300 patients per year. Each department has a dedicated group of physicians who look after the patients included in the Phase I-II trials and those who receive medication in compassionate use programs. The fellow will be involved in all steps of the patient's journey, from identification and discussion in the tumour boards, informed consent, screening, eligibility, participation, safety and efficacy evaluations, end of treatment and follow-up. The activity of the fellow will be supervised by a senior consultant. In addition, the fellow will be a member of the research team (and included on the delegation log) and will be participating in all non-clinical activities related to this, such as: SIVs, MVs, investigator meetings, audits, inspections. Lastly, fellows will participate in the Trial and Data Centrum (TDC) meeting every Monday where all patients included (and potential) in Phase I-II studies and compassionate use programs are discussed with all investigators, nurses, team leaders and trial support. Fellows will also be encouraged to develop SOPs for the internal functioning of the TDC. Fellows will attend the M4C (Maxima Comprehensive Childhood Cancer Center) meetings on Developmental Therapeutics and may also attend other disease oriented M4C based on their personal interests (e.g. AML, ALL).

2. Pre-clinical experience:

Fellows with special interest in a particular pre-clinical activity can be offered the possibility to join a lab in the Princess Maxima with whom they could develop a joint project.

3. Protocol development and Pharmacovigilance:

All fellows will have the opportunity to write a clinical trial protocol in collaboration with a senior investigator in the domain they are interested most. The Trial and Data Centrum (TDC) provides support to clinical research and has the capacity to sponsor clinical trials. An important component of the TDC is the pharmacovigilance department (safety desk); fellows will be trained and will participate in the roster of medical monitoring; medical monitors,

along with trial managers part of the safety desk, evaluate the safety elements of the studies for which we are the sponsors (e.g. SAE evaluations, SUSARs, safety reporting to authorities). Fellows will interact with the statistical department, finances, project management, and data management.

4. Regulatory issues:

By developing a clinical trial, fellows will be exposed to the regulatory aspects of clinical research. They will be involved in the submission process and reply to authorities. Eventually, fellows can be invited to participate as external attendees to the Ethics Committee meetings.

5. Ethics:

Fellows will be invited to participate in the Clinical Research Committee (CRC). The CRC is the multidisciplinary team in the Maxima who evaluates all clinical research project involving humans that are to be conducted in the institution. The CRC meets every two weeks. Designated members of the CRc review the proposals, including scientific but also ethical aspects. Fellows can be assigned the review of these proposals (supervised by senior investigators) and will be participating in the discussions.

6. Pharmacokinetics:

- The fellow will visit the pharmacology department to get insight in the practical aspects of pharmacology related to clinical trials. The pharmacology department will also be involved in the PK aspects of the protocol that the fellow will be doing.

7. Molecular targeting/precision medicine:

The fellow will join the molecular tumour boards once a week in the hemato-oncology department and the iLTB, an international molecular tumour board for patients with haematological conditions that takes place every two weeks. Molecular results are also discussed in the routine multidisciplinary tumour boards of every department (hemato-oncology, solid tumours and brain tumours) (twice per week).

8. Inmmuno-oncology

- The fellow will visit the cell therapy facility department and the CAR-T therapy (and stem cell transplantation).

9. Pharmaceutical industry:

- The fellow will be involved in the clinical trials that the Princess Maxima sponsors to get the experience to work with the pharmaceutical industries.