*Any COVID-19 measures issued by the Belgian authorities or by the hospital will prevail over this guidance for resuming clinical trial activities.*

*In addition, research activities must not in any way interfere or stress the hospital’s capacity to provide medical care to those in need.*

Study- or sponsor-specific instructions should be followed, provided that these do not conflict with the directives issued by the Belgian authorities, or those issued by UZ Leuven.   
Where feasible and allowed per protocol, remote visits will be conducted rather than face to face visits.

**Relaunch of clinical trial activities**

Research activities will be restarted through a phased approach:

**Step 1:** Gradual relaunch of urgent activities and activities with minimal impact on patients, medical staff and supporting departments and with limited need for personal protection materials, and low risk of contamination   
***>>> Starting May 18th 2020***

**Step 2:** Gradual return to appropriately adapted routine practice   
***>>> Starting June 8th 2020***, **provided that no additional restrictive measures related to COVID-19 will be introduced** either by Belgian authorities, or the hospital

What is permitted under Step 1?

Urgent activities:

* When required to assure the wellbeing of the patient, and further delays are no longer medically justifiable, new treatment modalities in the context of a clinical trial may be initiated or resumed per protocol
* To safeguard the patient’s health and/or to assure the validity of the trial data and/or safety/efficacy parameters, study visits (whether or not planned) can no longer be delayed

Activities with minimal impact:

* Activities that do not require physical interactions with patients, external visitors (e.g. monitors, service providers etc.) and hospital staff; including but not limited to:   
  data reviews, data entry, document reviews, retrospective research for which informed consent was already obtained, etc.   
  Of note: remote Source Data Verification is not allowed in Belgium (per FAGG)!
* Activities that do not require additional consumption of personal protection materials
* Activities that require no additional contact/interactions with hospitalized COVID-19 infected patients, in addition to the routine COVID-19 clinical care program.
* Activities that require minimal use of extra means and/or personnel (i.e. requiring only internal personnel, with no impact on clinical activities)

What is possible under Step 2?

Non-urgent activities:

* Audit visits and inspections
* Monitoring visits
* On-site initiation visits
* On-site study close out visits
* Actively (re-)starting study recruitment and/or finalizing previously started screening procedures and/or rescreening activities to obtain a new baseline, in view of study inclusion (notwithstanding urgent situations as stipulated above).
* Randomization of patients who completed all screening procedures prior to the introduction of nationwide restrictive measures due to COVID-19.
* Long-term post-treatment routine follow-up visits for studies and/or patient populations for which no or very little life-threatening medical complications are expected
* Off-site archiving of documents

High-impact activities:

* Activities that require physical contact with external parties, such as but not limited to external monitors, PhD and master students, interns etc.
* Study-specific activities that require use of additional hospital infrastructure, such as but not limited to functional assessments, medical imaging (except for urgencies, as specified above, and with separate patient flow), etc.
* Research activities that are competing with the hospital’s capacity for providing clinical care.

**Preventing further spread of SARS-COV-2**

COVID-specific directives issued by the Belgian authorities, and those issued by UZ Leuven must be complied with at all times, not in the least with regards to wearing a face cover and social distancing:

* The use of a mouth mask is obligatory for everyone visiting UZ Leuven.
* UZ Leuven visitors, including external monitors/clinical research associates must wear a mask covering their nose and mouth at all times.  
  Visitors are asked to bring their own face mask and disinfecting hand gel.
* Patient and monitoring visits must be organized with respect for social distancing directives and may not interfere with hospital’s capacity to provide medical care.
* Monitors/clinical research associates must be provided with an adequate workspace and the number of monitors allowed in the same room will be restricted to allow for social distancing
* Only one monitor/clinical research associate will be allowed per study