To:

16 March 2020

Pharmaceutical companies
Clinical trial Sponsors
Hospital Directors
Helsinki Institutional Committees

Subject: Guidelines for Sponsors, Investigators, Helsinki Committees and Hospital Directors regarding Medical Research Conduct in the Upcoming Period

Following the outbreak of the Corona virus and to enable, as far as possible, further research activity in Israel, the following are the guidelines for the upcoming period, which will be valid until the announcement of a return to routine:

When submission for application:

1 . New submissions can be sent to us on digital media + interface only no hard copy is needed, completions and amendments- required via interface system and Email (signed documents).

2. Electronic signatures can be used (if approved at the institutional level)

During study conduct:

1. The supply of the preparation to the patient's home, if necessary, in accordance with the Division's instructions, (the Pharmacy Division's announcement from date 11/03)
2. The investigational product may be delivered directly from the importer to the patient's home with the condition that the investigational product provided is taken / used by the patient independently.

The Sponsor must establish internal SOP procedures related to prevention of MIX-UP.

If the treatment requires a physician/ nurse, all efforts must be made in order to ensure that the patient will receive medical care from the appropriate medical institution.

3. If a hospital/ department cannot carry out the study in a hospital due to concern for Corona and the investigational product cannot be supplied to the patient's home, the patients will be able to receive treatment at a different medical center in coordination with the Sponsor and the hospital director. Alternatively, the Sponsor will be able to provide treatment by a professional in the patient's home.

4. Vital signs tests can be performed at the patient's home, digitally remotely, etc. according to the Sponsor's guidelines.
5. The new information can be transferred to a patient not in full consent form (meaning Patient Information Sheet including a summary of changes required until returning to routine). Also, in case of a patient staying in quarantine, the consent form / Patient Information Sheet can be transferred digitally with a condition that a receipt verification will be performed.

Clinical Trials Dept., Ministry of Health
P.O.B.1176, Jerusalem 9101002
Pharmaceuticals:
Tel: 02-5080246/78, Fax:02-6474865
clinicaltrials.pharm@moh.health.gov.il
Medical Devices & ATMP:
Tel.: 02-5080247 ,Fax: 02-6474864
clinical.trials.devices@moh.health.gov.il

קול הבריאות *5400

המחלקה לניסויים קליניים - משרד הבריאות
ת.ד.1176 ירושלים 9101002
תרופות:
טל: 02-5080246/78, פקס: 02-6474865
clinicaltrials.pharm@moh.health.gov.il
אמ"ר ותרפיות מתקדמות:
טל: 02-5080247 פקס: 02-6474864
clinical.trials.devices@moh.health.gov.il

6. Protocol deviations due to the corona outbreak are not considered as violation. The Sponsor must issue organized guidelines and procedures for the emergency period and to properly document the deviations.
7. The supply of investigational products must be taken care of in advance. If necessary, we will consider the possibility of mitigation of labeling for the purpose of maintaining a therapeutic continuum (a preparation that comes from abroad and is intended for clinical research and cannot be adjusted to the Israeli Packaging Regulations).
8. Changes to the study protocol resulting from dealing with the corona virus (such as virtual visit, digital activity, administrative or logistical changes will be sent to the institutional committees as "notifications" without the need for approval.
   At the same time, committees have the right to question the updates and request changes.
9. Other changes will be addressed as usual as today by the institutional committees.
10. Monitoring activities should be minimized to the minimum required in order to ensure patient safety and monitoring. Remote activities are preferable. These guidelines are subject to change and must comply with the Ministry of Health guidelines.

Institutional committee activity:
Institutional committees' conference can be held in a non-physical conference / conference call. Gathering, forum, discussion and documentation will be conducted as usual.

Raw materials for production:
If certain reagents cannot be imported for the characterization/ preparation of advanced therapy products, please consult us (for instance- there may be
antibodies that are good for characterizing the product but have not been validated for new imports).

Any additional questions can be consulted with the Clinical Trials team.

Regards,
Dr. Catherine Ella
Director of the Clinical Trials Department

Copy: Dr. Osnat Luxembourg, Head of the Medical Technologies, Information and Research Division
Magister Hadas Rotem, Director of the Pharmacy Department
Magister Eli Merom, Deputy Director of the Pharmacy Department
Dr. Ofra Axelrod, Deputy Director of the Pharmacy Division, and Director of the Institute for the Review and Standards of Medical Materials
Clinical Trial Department employees

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