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Turkish Medicines and Medical Devices Agency Published an Announcement regarding Measures to be Taken in Clinical Researches due to COVID-19 Pandemic

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On 20 March 2020, Turkish Medicines and Medical Devices Agency ("**Agency**") published an announcement ("**Announcement**") titled "Measures to be Taken in Clinical Researches due to COVID-19 Pandemic". The Announcement is for the researches falling within the remit of Clinical Researches Department.

Accordingly; within this period,

- By taking the characteristics of the researches (such as the researches in which immunosuppressive goods are used) into consideration, researches can be temporarily stopped or prematurely terminate if deemed necessary.
- In cases threatening the volunteers' security, emergency measures should be taken to protect them. If necessary, supporter and/or research team must implement emergency measures immediately. In such cases, there is no need to obtain permission from the Ethics Committee or the Agency.
- There may be more protocol deviation/violation than usual due to the measures taken. If deviations/violations are caused by COVID-19 measures, there is no need to notify the Ethics Committee or Agency. These notifications will be requested collectively as a list later. The Agency will announce the schedule and scope on its website.
- Based on risk assessments, monitoring plan may require some changes. Within this scope, the first choice should be the postponement of on-site monitoring activities, to avoid the increase in the researcher's and center's workload. Decisions should be made together with the team, by taking volunteer safety and research team's responsibilities into consideration.
- In cases where maintaining the monitoring activities in the center (such as possible quarantine, isolation situations) is not possible, remote monitoring can be carried out. When the COVID-19 measures are reduced/removed and life goes back to normal, the frequency of monitoring on-site activities should be increased and the impact of the decreased monitoring on-site activities should be evaluated.
- Given the possible obstacles, the safety margin specified in the legislation can be increased up to three times in order to ensure sufficient product supply to research centers.
- Proforma invoices shall not be physically requested for import applications. The Agency will e-sign and forward the proforma invoice attached to the application.
- In order to reduce the frequency of volunteers' center visits and avoid various risks, more products than usual may be given to the volunteers or to a relative visiting the research center instead of the volunteer at the scheduled visits. Direct product supply to volunteers from research product storehouses will not be accepted at this stage.
- In cases where abroad transfer of biological samples is not possible due to reasons such as customs restrictions, research center lab and/or local external laboratory facilities should be considered.

- Volunteer security should be prioritized when considering visits to centers.
  The visits should be planned in a way to reduce the center's and researcher's workload. They should be postponed if possible.
- In line with the general measures and the measures regarding collective organizations, only online researcher meetings will be allowed. In case face-to-face meetings cannot be held, Ethics Committee meetings can be performed online. Except for mandatory cases, an increase in the number of volunteers and center adding applications will not be accepted, within this period. Therefore, no application should be made in this regard.
- For the first applications, there is no need to submit physical documents to the Agency. All documents will be electronically submitted. Wet-ink signature is not mandatory and documents can be e-signed. E-signatures should be preferred for the documents that require a signature. For e-submitted documents with wet-ink signature, Agency will request the wet-ink version before giving the permission letter.
- For the ongoing researches, there is no need to submit physical documents to the Agency during applications. Wet-ink signature is not mandatory and documents can be e-signed. Physical documents shall be archived by the applicants and forwarded to the Agency in line with the schedule and the scope determined by the Agency.
- Letters will be prepared for the notification applications (notifications stated in the 4th chapter of Application Guide) (KAD-KLVZ-02) only if a deficiency is determined.

To sum up, the Announcement stated that within this period, volunteer safety is prioritized, the researches can be stopped temporarily or terminated prematurely; emergency measures can be taken for security; there may be more protocol deviation/violation than usual due to the measures. In this regard, face-to-face meetings shall be replaced by online/electronic meetings and physical document submission shall be replaced by electronic submission.

Please see the full text of the Announcement from this link. (Only available in Turkish)