

COVID-19 Implications for Clinical Investigations Needed for Medical Device Recertification

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During the challenging times of the COVID-19 pandemic, it is important to ensure that clinical investigations for existing and new medical technologies can continue with minimal disruption whilst preserving the safety of the participants and the quality of the data generated through the investigations.

For that reason, the European Commission, most EU Member States and the European Medicine Agency have published different guidance documents regarding the continuation of clinical investigations during the pandemic.

These guidance documents vary between countries and can significantly impact ongoing investigations in terms of enrolment, data collection, protocol amendments, operational oversight practices and monitoring activities. As a consequence, the time required to complete the investigations and start using the obtained data are impacted.

In view of this situation, joint efforts are needed from all stakeholders:

- **We call on the European Commission to recognise the below-mentioned challenges and consider issuing a recommendation allowing flexibility in meeting the Post Market Clinical Follow-Up (PMCF) regulatory requirements.**
- **We prompt national Health Authorities and Notified Bodies to align on a common harmonised approach for the renewal of CE certificates affected by a delay and/or deviation in the planned PMCF) activities if deviations and completion delays occur due to the COVID-19 pandemic.**
- **Manufacturers commit to do their utmost to implement mitigation plans and/or provide the PMCF data upon availability as agreed with the respective Notified Body.**

Medical technology industry approach

With relation to the continuation of new and ongoing clinical investigations for medical devices, the medical technology industry performs risk assessments as mandated by the EMA and national authorities' guidelines, and implements mitigation measures to manage the COVID-19 pandemic while keeping the clinical investigations running and safe for all parties involved. This is done in close collaboration with investigators to limit the possibility of COVID-19 infection.

Due to the above described situation possible changes of original clinical investigation plans could include but are not limited to the following:

1. Adapting follow-up physical visits by the study participants (patients) into phone / video visits;
2. Collecting data at a later stage when it is safe for patients to return for a physical visit and delaying and extending timeline for data collection;
3. Accounting for delayed study start and slow enrolment by amending study protocols and statistical analysis plans.

Impact on clinical investigations and recertification of medical devices

Despite possible adaptations to the investigation plans, one can expect that the clinical investigations' progress and outcome will be impacted due to factors such as:

- Suspending or slowing down recruitment of participants due to significant decrease of procedures across all EU countries and healthcare institutions;
- Temporary halt at some or all investigation sites;
- Postponement of investigation start or site activations (i.e. due to administrative constraints);
- Possible (significant) protocol changes requiring approval of Ethics Committee and the Institutional Review Board and, as applicable, the relevant health authorities;
- Patients not willing to continue participation;
- Patients missing follow-up visits due to lock-downs, being afraid etc, resulting in significant drop-out rates; potential need to replace participants;
- Fewer participating patients, later completion of the investigation and delayed data availability.

Post Market Clinical Follow-Up data and impact on recertification

An additional concern of the medical technology industry is that the legally required Post Market Clinical Follow-Up (PMCF) plan for a medical device on the market may require a specific completion date to gather relevant evidence for the renewal of an existing CE certificate. Those PMCF activities and studies might not be completed in time due to the delays caused by the Corona pandemic.

Delays and changes of PMCF activities could have significant impact on the regulatory compliance and CE recertification, potentially impacting the continued availability of medical devices that are on the market today.

MedTech Europe would be glad to engage in a timely discussion with the European Commission, Member States and Notified Bodies to find practical solutions for the above-mentioned measures to avoid any delay in the implementation of the medical device recertification procedures.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

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