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COVID-19 Impact on Biopharma Clinical Development in the EU and Mexico Episode Guide

- Impacts of COVID-19 on the Management of Clinical Trials
- Significant regulatory developments to deal with COVID-19 Impact

Impacts of COVID-19 on the Management of Clinical Trials in the EU

- Some ramifications during the first wave of the crisis:
  - Pcould not access hospitals
  - Staff were being assigned to COVID-19 related work
  - Trial subjects dropping out, getting sick or at risk of contracting COVID-19
- One major impact is the direct to patient delivery of medicine or auxiliary product used in a clinical trial
  - Usually a trial patient would get his treatment on the investigational site under the supervision of an investigator who takes care of all medical decisions related to trial subject
  - COVID-19 caused a handful of issues which hindered trial subjects from going to the trial site and obtain treatment, this allowed for the rules to be relaxed and direct shipments to clinical trial participants have been permitted as long as certain conditions are met

Impacts of COVID-19 on the Management of Clinical Trials in Mexico

- Lack of digitalization was evident and increased the impact of COVID-19 in Mexico and across Latin America
- Regulatory delays increased during the pandemic because of the suspension of governmental operations with COFEPRIS's work capacity reduced to 30% due to difficulty in transitioning to remote working
- Public bodies involved in clinical trials were also heavily affected including National Commission of Ethics and the New Molecule Committee
- Hospitals and physicians were saturated because of the lack of implementation of electronic health records or telemedicine - those conducting clinical trials could not access the research sites as these have been converted to COVID-19 facilities and validation of data could not be concluded

Significant regulatory developments to deal with COVID-19 Impact in EU - Direct to Patient Delivery

- European Medicines Agency and Heads of Medicines Agencies issued a guidance for the management of clinical trials during the COVID-19 pandemic in an effort to harmonize the different guidance put together by the Member States
- The European guidance states that direct from sponsor to trial participant of Investigational Medicine Products (IMP) delivery is accepted in a few member states under this situation but the sponsor should check the national guidance - though this is still prohibited in some member states such as Belgium
- What is possible in Belgium is that medicine can be shipped to trial participant under the responsibility of the principal investigator (from the site to the patient home) provided that:
  - the product is suitable for transportation and for storage at the home of the patient
  - the sponsor conducts a risk assessment on any of the these changes, and consideration on whether specific training or information must be given to the patient or if a qualified healthcare professional must go to the patient's home and administer the product
- Data protection confidentiality must also be taken into account
  - Belgian regulator does not allow that any data is shared to the sponsor or distributor
- There is a need to conduct a risk assessment and involves changes to the protocol - the way these changes are handles differ on a country-by-country basis
- Because of this, there is an interest to turning this direct shipments into a future business model with specialized service providers offering this to service to sponsors or CROs

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Significant regulatory developments to deal with COVID-19 Impact in Mexico

- Response of federal government was slow and no new comprehensive guidelines have been issued
- Government set up a priority list of approvals as certain treatments and medical devices were critical during the pandemic
  - approval of diagnostic tests - critical for some clinical trials
  - ventilators and medical devices important in treating COVID-19 patients
  - clinical trials for COVID-19 patients needed to get priority treatment
- Clinical trials not related to COVID-19 did not receive any guidance or new developments and some new clinical trials being planned have been suspended as a result of this

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