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The impact of COVID-19 on Clinical trials

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Response to COVID-19

- Cancel, delay or submit a temporary pause on Clinical trials with non-critical patient populations ~ 80% *(The Lancet)*
- Temp halt on recruitment for ongoing studies to allow healthcare professionals to focus on already enrolled subjects
- Pause on any Ph1 healthy volunteer trials
- Avoid/minimise visits to the trial sites:
  - Direct IP shipment to patients
  - Home administration
  - Remote monitoring
  - Remote informed consent
  - Remote lab collection
  - Extended patient visit windows
- Sponsors required to perform continued risk assessments on all ongoing trials
- Non-acceptance for VHP and EU country pilots

Health Authority Focus

- COVID-19 clinical studies fast tracked under the Emergency use programs
- Expedited scientific advice timelines and shorter review timelines for COVID-19 related studies and COVID-19 Diagnostic test kits
- Health Authorities (HAs) that were previously requesting Clinical Trial Applications on paper or CD now accept electronic submissions
  - Faster delivery and more accessible for assessors working from home
- Priority for submissions related to drug shortages or disruption of supply i.e. change of manufacturers, supplies, release sites etc that may have been diverted due to country lockdowns.
- Validity of GMP, GDP certificates and Manufacturing/import authorisations extended until end of 2021
- Allowed remote GMP inspections and batch certification
- Routine inspections were temporarily postponed
- Increased number of protocol violations have been acceptable.
- HAs requested that all non-critical studies were not submitted during the height of the pandemic to reduce the burden

The impact on future Clinical trials?

- New/revised regulatory guidance available on clinical trial management during a pandemic
- Fast track, streamlined review of studies for emergency use
- Remote studies will be more acceptable in the future:
  - Reduce burden at trial sites
  - Reduce burden for patients – improved patient engagement, reduced travel and time of work, collection of data through wearable devices, online patient diaries etc
  - Increase geographical diversity.
- Short term delays in patient enrolment and recruitment - 30-70% decline
- Delays in clinical trials = delay in bringing drugs to market
- Shorter periods of patent exclusivity
- Impact on pricing negotiations – cash strapped governments
- Long term financial impact on companies

Thank You

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