IMPACT ASSESSMENT FOR CURRENT TRIALS & FORECAST FOR BEYOND THE PANDEMIC

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WHAT WAS PREVIOUSLY VIEWED AS RISK, WILL NOW BE SEEN AS RISK MITIGATION.
What **counter-measures** can be deployed immediately to provide continuity for current studies?

What is your **forecast** for when the delayed study starts will come back online?

How do we ensure that the **innovation** being accelerated today outlasts the pandemic?
TRIAL STATUS

Lilly Provides Update on Clinical Trial Activities During COVID-19 Pandemic
March 23, 2020

INDIANAPOLIS, March 23, 2020 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today provided an update on the company’s clinical trial activities in light of the COVID-19 pandemic. The company will delay most new study starts and pause enrollment in most ongoing studies. Lilly is continuing ongoing clinical trials for patients who are already enrolled.

1. New study starts are delayed
2. Enrollment is paused
3. Enrolled participants continue
Guidance on the Management of Clinical Trials during the COVID-19 (Coronavirus) pandemic

Version 1 (26/03/2020)

The European Medicine Agency (EMA), Good Clinical Practice (GCP) Inspections Working Group, the Clinical Trials Transformation Initiative (CTTI), a working group of the Heads of Medicines Agency (HMA), the Clinical Trials Expert Group (CTEG), a working group of the European Commission representing EMA/Committee for Medicinal Products for Human Use (CHMP) and the European Commission on behalf of the EMA, the GCP Inspections’ Working Group for harmonized EU/EMA guidance on the impact of the COVID-19 pandemic on the conduct of clinical trials.

The situation is evolving, and pragmatic actions may be required to deal with the challenges of conducting research and enrolling participants. The points mentioned below are intended to provide guidance for all parties involved in clinical trials during this time.

For questions on clinical trial conduct during the COVID-19 pandemic, please email ClinicalTrialsCovid19@ema.europa.eu.

Sponsors and investigators need to take into account that there might be specific national legislation and guidance in place, which they should consult and which can be used to complement this guidance, or, where respect to particular matters may take priority over these recommendations. This document is not intended to replace guidance for individual countries or regions, which should take into account the specific needs and priorities.

*The word “participant” is used in this text as a synonym for the term “subject,” defined in Directive 2001/20/EC as “an individual who participates in a clinical trial as either a recipient of the investigational medicinal product or a control.”*
TRIAL CONTINUITY

- Investigational Product
- Clinical / Safety Monitoring
- Patient Visits & Data Capture
TRIAL CONTINUITY

Investigational Product
- Direct-to-patient supply chain
- In-home infusion

Clinical / Safety Monitoring
- Remote/ central monitoring
- Data-driven/ risk-based monitoring

Patient Visits & Data Capture
- Video/ tele-visits & home visits
- Shifting endpoint to digital (sensor, eDiary, etc)
- Opportunities for modeling for missing data

What is “new” is not the tools, It is their rate of adoption.
ADDITIONAL NEAR-TERM OPPORTUNITIES

**Patient Communications**
- Ensure robust communication with patients to reduce anxiety and minimize attrition

**Participant Screening**
- Resume online screening of potential new participants, including time-intensive sourcing of medical records to build high-quality screening pools

**Further Optimizing New Studies**
- Use the “gift of time” to ensure new protocols are robust to avoid future amendment delays
- Engage with and listen to patients!

Ensure a plan for documentation!
MID-TERM QUESTIONS

- Which studies will not be able to continue?
- How will regulatory reviewers handle significant protocol deviations or missing data?
- Will regulators continue inspections?
- Will US, EU and ROW interpretations vary?
- When will new study starts resume?
- Will mid-size CROs survive the delays?
- Will investigator sites survive the delays?
- Who will be ready when new studies resume?
HOW DO WE RETAIN THE
BEST OF THE CHANGE TODAY,
WHEN WE GET TO THE
OTHER SIDE OF THE CURVE?
LONG-TERM IMPACT

• Will Innovation Outlive the Pandemic?
  • Only with commitment from us all
  • Lasting change requires enterprise commitment
    (adapting policies, selecting partners, designing studies differently)

• Decentralized trials, Digital endpoints, Remote/ Central monitoring, etc.
  • Will be viewed as risk mitigation
  • Will be consistently incorporated as first-line or second-line
Resource List for Study Teams Managing Patient Visits for Trials During Coronavirus Pandemic

Links below to support study teams working on clinical trial continuity and maintaining drug supply, clinical/safety monitoring, and remote patient visits. Please contact me if you need direct contacts at any of the listed organizations or if you have recommended additions/edits to the list.
- Craig Lipset (craig@lipset.com)

Disclaimer
This is a dynamic and growing shared list of publicly available resources and company information. Inclusion on this list is for informational purposes only and not an endorsement of quality or capability.

Visiting Health Care Providers
- Hawthorne Effect (https://www.hawthorne-effect.com) -- HERO Network of healthcare professionals across the US.
- Medical Research Network (https://www.amrnetwork.co.uk) -- Home research support with resources including research nurses and study coordinators, citing study conduct in North America, Europe, and Asia.
- Sengului Biosciences (https://www.sengulbiosciences.com) -- Adaptable mobile healthcare workforce for clinical trial home visits in US, Canada, and parts of Europe.
- Coram/CVS (https://www.coram.com/manufacturers) -- Over 800 high-acuity nurses across the US to support in-home participation.
- GlobalCare (http://globalcare-direct.com) -- Global clinical network of ambulatory clinicians and country coordinators for trials in the home or alternative site settings.
- Sorenson Clinical Research (https://www.sorensonclinicalresearch.com/) --...