The Impact of COVID-19 on Clinical Trials

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How COVID-19 Has Taught Us to Streamline & Simplify Clinical Trial Processes
COVID-19 has shaken up clinical trials worldwide.

Medidata recently analyzed the effect of how COVID-19 has affected research (particularly patient enrollment); 4,599 studies and 182,321 study sites were reviewed, results are below:

- An average 65% worldwide decrease; this decrease is not uniform.
  - Japan experienced 43% decrease
  - India has shown an 84% decrease
  - The U.S. is down an average of 67%

What the results show us:
Clinical Trials are particularly vulnerable to the state of public health!
The impact of COVID-19 is not uniform across countries or therapeutic areas.

- Enrollment in studies for respiratory diseases decreased by 34%
- Enrollment in endocrine diseases decreased by 80%
- Additional areas of decline:
  - Oncology 48%
  - Dermatology 64%
  - Central Nervous System 68%
  - Cardiovascular Diseases 70%
Obstacles

- Mobility and Travel
- Technology
- Supply Chain
- Situations at sites are changing day-to-day and even hour-by-hour
- Monitoring
- Patients weary of enrollment
What can we do?

- Develop a COVID-19 plan and distribute to sites. Plans should be fluid so they can be updated easily.
- Streamline processes: what steps are essential, what can be put on hold?
- Document, document, document – always important but now more than ever
- Keep all lines of communication open
Thinking outside the box

- Shift the mix to lower-impacted countries and regions
- Get virtual – conduct clinical trials remotely, includes remote consenting and patients remote health monitoring (and in-house services)
- Deliver what is needed
FDA and EMA has given sponsors increased flexibility. Staff should be trained to over document their thought processes and be prepared to explain to regulators later!

Best practices that emerge during the pandemic will likely carry forward once COVID-19 has passed. (I hope that remote monitoring will be one of them)
What are we doing?

- 100% virtual – remote SQV, SIV, Training and Monitoring
- Utilization of technology
- Modified timelines
- Increase frequency and types of communication
- Modified SOPs and documentation
COVID-19 Impact on Studies

% of sites Restricting CRA Access

Asia Pacific: 49.4%, 55.0%
Europe/Africa: 61.7%, 90.6%
Latin America: 90.6%
North America: 80.1%
Response to COVID-19 Trial Impact

- Immediate triage of all active clinical trials
- Assessment of impact on Patients
  - Country by country impact of travel restriction/SIP laws
  - Target populations on active therapy vs follow up
  - Schedule of Events – Critical Endpoints, Safety Endpoints
  - Ability to move in-person to virtual/in-home visits
    - Remote Patient Monitoring/Connected Devices/Telehealth
  - Availability of Home Health Nursing
Response to COVID19 Trial Impact

- Assessment of Impact on Data
  - Site Access for SDV
  - Remote EHR access
    - Technology/eSource
  - Scanned Document access
  - Regulatory views on redacted data option
Running COVID19 Trials

- Key to success has been Virtual/Decentralized Clinical Trial Models
  - Mobile Health Platforms
  - Connected Devices/Telehealth/Wearables
  - Willingness across all stakeholders to expedite process
    - Site Contracts
    - Regulators
    - IRBs/Ecs
    - Ability to modify process and SOPs
COVID19 Trial Case Study

- 34 days from first contact
  - 293 sites contacted globally
  - 163 sites activated in 19 countries
  - 817 patients dosed – in patient ICU

- UNPRECEDENTED TIMELINES
  - Average IRB/EC – 3.1 days TAT
  - Average contract – 8.5 days TAT
  - Average activation time total – 14.4 days
Power of Virtual Trials During COVID-19

- A model to keep potentially infectious patients out of healthcare environments is critical.
- A model to keep immunocompromised patients free from COVID exposure is critical.
- Telehealth access and use by patients has increased 1000+% in some cases.
- Virtual/Decentralized Trial models are the key solution.
Industry First, 100% Virtual/Decentralized Interventional, registrational, drug trial

- 100% Virtual/Decentralized Trial
  - Heart Failure Population
  - Interventional, Registrational Phase 3 Trial
  - Recruitment, Enrollment, Treatment, Data Collection, Follow UP – 100% siteless
  - Endpoints collected via wearables and ePRO

- Trial started amidst the height of COVID19 site closures
- In 24 days, 6 IDN’s activated, 11 in Process
- 600+ patients contacted with 200 screened, approx. 50 randomized
Fully integrated mobile ecosystem is key for Virtual Trials during Covid-19
More Than Just Technology

STUDY PORTAL
- Site/Sponsor Dashboards
- Global compliance
- Compliance by sites at countries
- Real-time analytics
- 3rd party integrations

User / Role Management
Treatment Plan Management
eConsent
Surveys
My Health Status
Adherence & Reminders
Patient Diary
Remote Patient Monitoring
Video & Chat
Appointments
eCOA/ePRO
Modularized Study Components

Loosely Coupled Services/Micro-services
Modular UI Components

Integration & Orchestration Layer

Platform Services
Tenancy Model
PaaS

Secure data
Data Visualization
Data Management

PRA Portal
Study Operations

- GMP
- HIPAA
- ISO 13485
- SOC 2
- OSHA Compliant
- 21 CFR Part 820
- 21 CFR Part 11
- EU Annex 11
- GAMP® Cat 4 GxP
COVID19 and its impact on clinical trials is not likely to end within the next 12-18 months, although impact will vary

The potential for a 2\textsuperscript{nd} Wave of COVID19 coupled with Influenza has the potential to have an even greater impact on trial site access for patients.

Patients regardless of disease will continue to expand use of telehealth – and reimbursement will drive this behavior.

Connected health and in-home monitoring tools will allow for data and endpoints to be collected from home.

Protocol and trial design moving forward MUST focus on virtualizing as many visits as possible if they are to succeed in recruiting patients in the COVID19 era.