The Impact of COVID-19 on Clinical Trials

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How COVID-19 Has Taught Us to Streamline & Simplify Clinical Trial Processes

Current state of Clinical Research

- 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!

Current state of Clinical Research

- 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

The Regulations

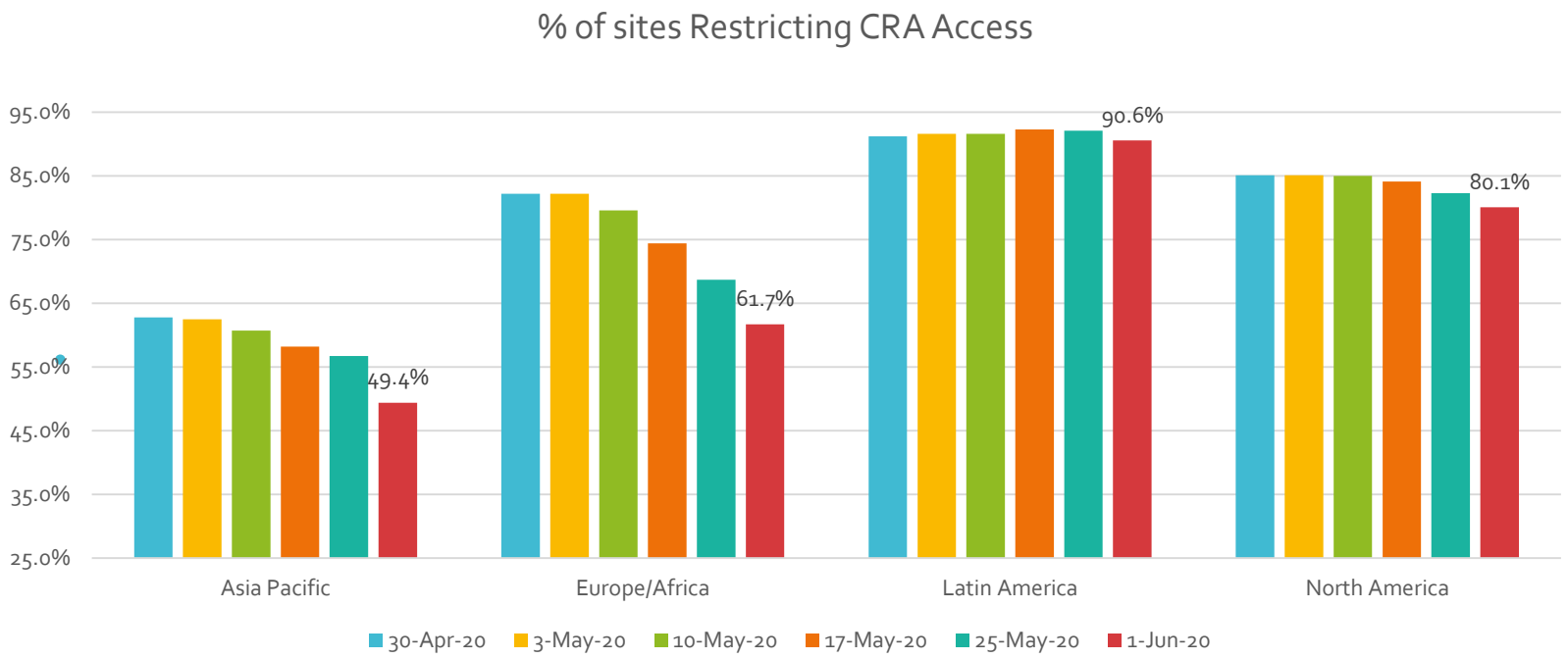
- FDA and EMA has given sponsors increased flexibility. Staff should be trained to over document their thought processes and be prepared to explain to regulators later!
- Best practices that emerge during the pandemic will likely carry forward once COVID-19 has passed.

  (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

COVID19 Impact on Studies



Response to COVID19 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 EAP

- 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 COVID19

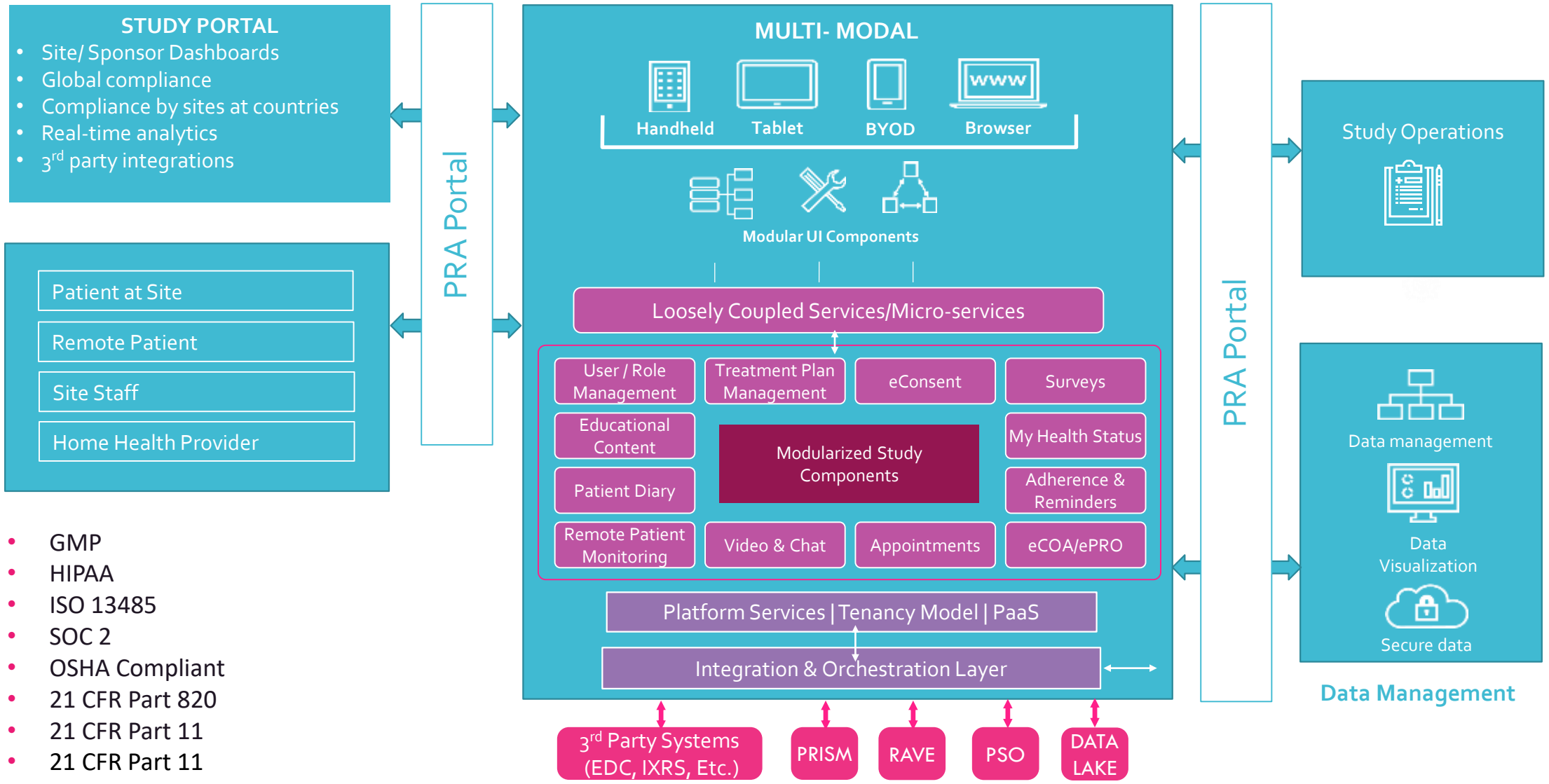
- A model to keep potentially infectious patients out of healthcare environments is critical
- A model to keep immunocompromised patients free from COVID exposure is critical.
- Telehealth access and use by patients has increased 1000+% in some cases
- Virtual/Decentralized Trial models are the key solution.

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 Covid19

More Than Just Technology



- GMP
- HIPAA
- ISO 13485
- SOC 2
- OSHA Compliant
- 21 CFR Part 820
- 21 CFR Part 11
- 21 CFR Part 11
- EU Annex 11
- GAMP® Cat 4 GxP

The New Normal The Post COVID19 World

- 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 2nd 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.