Clinical Trial Continuity in the Wake of a Pandemic

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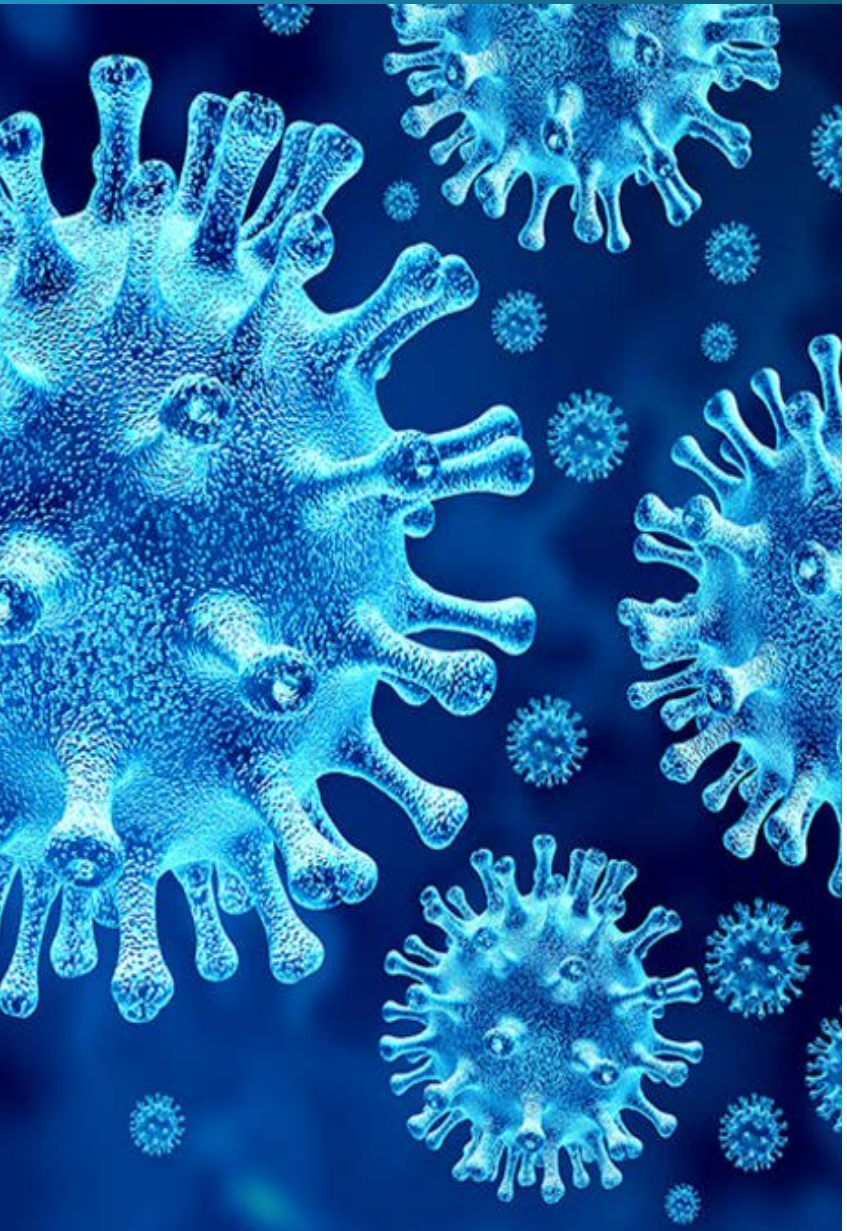

March 2020

National emergency declared due to COVID-19 public health emergency. Several Acadia trials were ongoing at various stages of development at the time:

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Rett syndrome:
Actively recruiting (Ph3) + Open Label extension

US only

Advance 2

Schizophrenia:
Active Open Label extension, Ph3 in startup

Ex-US only

Existing Acadia protocols were not designed for remote visits

"And, while there's no reason yet to panic, I think it only prudent that we make preparations to panic."

Future-Proofing the Protocols

Amendments included provisions to permit off-site assessments

Rett syndrome: lavender

- At-home visits by mobile nurses or site staff (ECG, vitals, weight, blood collection, etc)
- Off-site laboratory evaluations (eg, local lab, commercial labs, in-home phlebotomy, etc)
- Remote efficacy ratings via telemedicine/ video-calls, web portals

Schizophrenia: Advance 2

- At-home visits by site staff/ raters to perform ratings in person
- Off-site laboratory evaluations (eg, local lab, in-home phlebotomy, etc)
- Remote efficacy ratings via telemedicine/ video-calls

Future-Proofing the Operations

Site engagement and operational logistics adapted to “new normal”

- Investigator townhall meetings via Webex/ Zoom (periodically)
- “Virtual coffee” chats (1:1) and surveys to assess operational status, resources, morale
- Budget adjustments due to COVID (eg, PPE, testing, remote monitoring support, etc.)
- Remote monitoring plans, where appropriate (ie, GDPR considerations in EU)
- Web portals to facilitate secure, document exchanges
- Exploration of new tech/ devices (eg, portable ECGs)
- Video-conferencing licenses for sites (eg, Zoom for Healthcare) **[US only]**
- Expansion of mobile nursing services for at-home safety visits **[US only]**
- Direct-to-patient (DtP) drug shipment **[US only]**

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Investigator Feedback

Remote visits help free up clinic calendars where scheduling is an issue

Flexibility & convenience of off-site visits for Rett patients

Questions raised regarding mobile nurse responsibilities

Remote monitoring (SDV) requires extra labor

Video required for most assessments (eg, non-verbal cues)

Investigator Feedback

- Both sites and patients prefer in-person interaction (“more personal”). Telemedicine visits used as a last resort
- Patients with schizophrenia are generally suspicious of new or unfamiliar technology
- Poor WiFi or internet connectivity make video-conferencing a challenge (e.g., Eastern EU)
- Efficacy ratings may be difficult to assess over video; Some ratings like NSA-16 cannot be assessed over telephone (audio)
- Scheduling issues - subjects tend to forget remote visits are scheduled
- Privacy – remote visits are interrupted by other persons at subjects’ home

Advance 2

Clinical Trial Performance

RETT SYNDROME PROGRAM

- Enrollment in double-blind study paused from March to June 2020
- Open-label extension study was ongoing with few disruptions in treatment
- Exceeded adjusted enrollment targets
- 230 remote assessments completed

SCHIZOPHRENIA PROGRAM

- Double-blind study initiated in July 2020
- Virtual investigator meeting
- Site activations slightly delayed however enrollment targets met
- Open-label extension study was ongoing with minimal early discontinuations
- 25 remote assessments completed

Success Factors

Flexible protocols benefit sites and patients

- Incorporate provisions for remote assessments into original protocol rather than face amendments later
- Consider mandatory in-clinic visits (eg, SCR, BL, EOT)
- Require telemedicine visits to be subject to sponsor approval

Engagement of mobile nursing & third-party staffing services

- Define scope and responsibilities with PI agreement
- Gauge effectiveness of service through surveys

Investment in future-proof technology

- Cloud-based vs. hardware-based solutions
- Video-conferencing > audio-conferencing
- Digital health products (eg, wearables)

Key Takeaways

The Future is Bright

- No one-size-fits-all solution
  - Evaluate patient population and regional differences (US ≠ EU)
  - In-clinic interactions will never be fully eliminated (ie, consider hybrid approach)
- Engage investigators in the trial plans & decision-making
  - Up-front planning is key (eg, Direct-to-Patient drug shipment; staffing services)
- Budget Implications
  - Off-site assessments do not always translate to cost savings
- Patience, not just Patients
  - Adoption of new technologies and processes continue to grow