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Advisor and Founder
Clinical Innovation Partners

Ask questions in real-time by tagging @CraigLipset and #AHPsummit20!
Virtual Clinical Trials: Care from Anywhere

Alliance for Health Policy
2020 Signature Series
Voice of the Patient
20 October 2020

Craig H Lipset
@craighlipset
Agenda

Pre-COVID Trial Trends

Early-COVID Trial Continuity

Mid-COVID Trial Stabilization

Forecasts for Beyond
Clinical Trial Trends
Pre-COVID
Clinical Trial Trends Pre-COVID

TRIAL DIGITIZATION

- Real World Data / Real World Evidence
- Artificial Intelligence
- Mobile / Digital Endpoints
- Automation

PATIENT-CENTRICITY

- Participant Experience
- Information Resources
- Study Access
Early-COVID
Trial Continuity

OBJECTIVE:
Monitor Patient Safety
Avoid Missed Doses
Avoid Missing Data

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
Opportunities for modeling
Early Shifts in Trial Conduct

79% of SPONSORS/CROs Increasing Virtual
How has COVID-10 and associated lockdowns impact your use of decentralized trials?

90% of PARTICIPANTS Impacted
What changes have you experienced in your clinical trial as a result of the COVID-19 pandemic?

- Use of telemedicine: 42%
- In-person clinic visits to virtual clinic visits: 34%
- Suspension of clinical research study: 26%
- Study medication delivered directly to home: 21%
- Use of smartphone apps: 21%
- Reduced number of in-person clinic visits: 11%

Clinical Trials Europe, May 2020, n=184
CISCRP 2020, n=38
SOP Waivers & Protocol Deviations Do Not Make A “New Normal”

What Drove The Change?

Will The Change Last?

Culture still risk averse, only the environment changed.

What had been viewed as risk months early, now became risk mitigation.
Mid-COVID Trial Stabilization
Sites Anticipated Difficulty Resuming Studies

Clinical Research Sites Open to Enrollment

What is the Most Important Challenge in Restarting Clinical Trials at Sites?

- Restarting participant enrollment: 39%
- Participant willingness to return to the clinic for visits: 29%
- Having all necessary employees: 10%
- Having all necessary lab resources: 8%
- Assessing the impact on previously gathered clinical trial data: 8%
- Drug supply availability: 7%

Source: WCG CenterWatch™
Mid-COVID
Trial Stabilization

Committing To Change

Policies & Procedures
Partners & Vendors
Training & Culture
Rethinking Protocols
By July Most Sites Indicate Committing to Change

How are sites using telemedicine for trial participants?

- **BEFORE COVID-19**: 72% (rarely or never)
- **DURING COVID-19**: 64% (sometimes, often or always)

Will sites use telemedicine after COVID-19?

- **Yes**: 73%

How Are Sites Using, Or Planning To Use, Remote Coordinators?

- **BEFORE COVID-19**: 15%
- **DURING COVID-19**: 40%
- **POST COVID-19**: 61%

Source: WCG CenterWatch™
Home nursing visits would make participation in a trial somewhat/very appealing.

CISCRP Perceptions & Insights Study, 2019

Race/Ethnic Differences in Preference

- 85% Black
- 81% White
- 75% Hispanic/LatinX
- 66% Asian
58%

Percent of Patients More Likely To Participate In A Trial That Offers Telehealth Services.

SubjectWell Patient Attitudes Survey, May 2020

60%

Percent of Japanese Research Participants That Would Value Alternatives to Hospital Visits.

Continuum Clinical / 3HMedi Survey, May 2020
Drug trial (tolterodine tartrate)
Fully remote/virtual

A Clinical Trial From Home

REMOTE:
Research on Electronic Monitoring of OAB Treatment Experience
Safety & efficacy of Detrol LA for overactive bladder
600 patients from 10 states
2 lab assessments
5 mobile based e-diary assessments
Contemporary Clinical Trials
Volume 38, Issue 2, July 2014, Pages 190-197

Web-based trial to evaluate the efficacy and safety of tolterodine ER 4 mg in participants with overactive bladder: REMOTE trial

Miguel Oriol, Craig H. Lipstein, Bradley P. Jacobs, Anthony J. Costello, Steven R. Cummings

Fig. 2. Electronic data collection and management. EDC = electronic data capture, IVRS = interactive voice response system.

Fig. 3. Participant disposition. Percentages at each step of recruitment were calculated using the number of participants who viewed the study introduction web page as the denominator. Percentages at each step of screening were calculated using the number of participants who reconfirmed their e-mail address as the denominator.
Hybrid Trials

What changes are you making to existing trial models to address the challenges of the COVID-19 pandemic?

- 75% Incorporating some virtual trial elements
- 11% No changes
- 7% Going completely virtual
- 6% Other: Please specify

 Brick-and-Mortar Sites
Conventional investigator site visits

 Hybrid Studies
Some visits scheduled at home

 Fully Virtual
All visits from the home

ERT Survey Report: Virtual Trials and the COVID-19 Pandemic
Forecasts for Beyond
Post-COVID
Everything is Hybrid

People expect
CHOICE
in engagement
US online grocery went from 3-4% of grocery spending earlier this year up to 10-15% at the pandemic peak.

As the crisis recedes expect online grocery to level at 5-10%.

Bain & Co
## The Researcher’s View of Hybrid Trials

<table>
<thead>
<tr>
<th>Protocol-defined Location</th>
<th>Visit #1</th>
<th>Visit #2</th>
<th>Visit #2</th>
<th>Visit #4</th>
<th>Visit #5</th>
<th>Visit #6</th>
<th>Visit #7</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-Clinic</td>
<td>At-Home</td>
<td>In-Clinic</td>
<td>At-Home</td>
<td>In-Clinic</td>
<td>At-Home</td>
<td>In-Clinic</td>
<td>In-Clinic`</td>
</tr>
</tbody>
</table>
The Researcher’s View of Grocery Shopping

<table>
<thead>
<tr>
<th>Visit #1</th>
<th>Visit #2</th>
<th>Visit #2</th>
<th>Visit #4</th>
<th>Visit #5</th>
<th>Visit #6</th>
<th>Visit #7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grocery-defined Location</td>
<td>In-Store</td>
<td>At-Home</td>
<td>In-Store</td>
<td>At-Home</td>
<td>In-Store</td>
<td>At-Home</td>
</tr>
</tbody>
</table>
Next Generation
Hybrid Trials

Trials with Choice

Adapt to Patient Preferences & Journey
Path Forward for Research Sponsors

Fit-For Portfolio Solutions

- External Environment
  - Partner solutions
  - Competitive intelligence
  - Environmental risk
  - Regulatory perspective

- Internal Environment
  - Therapeutic areas
  - Patient insights
  - Geographic footprint
  - Culture

Build a Tookit of Decentralized Methods...

- eConsent
- Home health
- Local labs
- Local imaging
- Video visits
- Remote monitoring
- Central site
- Home drug supply

...To Pair With Portfolio and Patient Needs