Sites Matter: Industry Collaboration

1. CTTI - Industry Projects
2. Engagement of the Diverse Population
3. Site Payments
4. Site Study Dashboard
5. Contracts
6. Public Awareness
Faculty Disclosure

In compliance with ACCME Guidelines, I hereby declare:

I have no financial/other relationships with the manufacturer(s) of commercial product(s) or provider(s) of commercial service(s) discussed in this educational activity.

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Society for Clinical Research Sites, Inc. is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center’s Commission on Accreditation. Earn up to 17 CEUs, Nursing CEUs and CMEs (11 for Summit attendance & 2 per Master Workshop).
Transformations Coming to a Site Near You

Jennifer Goldsack
Clinical Trials Transformation Initiative
Clinical trials in crisis
Public-Private Partnership
cofounded by Duke University & FDA
involves all stakeholders
80+ members

To identify and drive adoption of
practices that will
increase the quality and efficiency
of clinical trials
<table>
<thead>
<tr>
<th>PROJECT PORTFOLIO</th>
<th>Systematic approach to evidence generation including use of non-traditional CT data sources &amp; technical innovations</th>
<th>Patients as equal partners across the R&amp;D continuum</th>
<th>CTs designed with a focus on efficiency &amp; quality</th>
<th>Trials that address emerging public health concerns</th>
<th>Safe &amp; ethical trials that are streamlined</th>
</tr>
</thead>
<tbody>
<tr>
<td>September 2016</td>
<td></td>
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</tr>
</tbody>
</table>

**Project Recommendations/Findings Complete**

- Large simple trials
- GCP training
- Monitoring
- Quality by design
- Recruitment
- Site metrics
- Anti-Bacterial Drug Development (ABDD):
  - Streamlining HABP/VABP trials
  - Opioid

- Central IRB (2)
- Data Monitoring Committees
- Informed Consent
- Safety reporting (3)

**Active Projects**

- Registries
- State of clinical trials
- Mobile Clinical Trials:
  - Devices
  - Leg & reg
  - Novel endpoints
  - Stakeholders
- Patient Group & Clinical Trials
- Investigator turnover
- GCP follow on (Qualified inv)
- ABDD:
  - Peds
  - Pilot studies
  - Unmet need
- Pregnancy Testing

**Completed Collaborations**

- Uses of electronic healthcare data
- Clinical trial survey
- CV endpoints
- Investigator training course
- Patient engagement survey

**Active Collaborations**

- Supporting IMPACT-AFib
- ABDD PTN
Investigator Turnover Project
An enormous amount of time and resources are expended by clinical trial investigators, sponsors, and others to initiate new investigators into the clinical trial process.

40% of Investigators are One and Done
Analysis of FDA Form 1572s ("Statement of Investigator) indicate a high turnover of investigators, approximately 40%.

The high rate of attrition and the initiation of new investigators impact site and overall trial performance.
Top reasons why one & done investigators leave research (survey)

- Too much time required to lead trial
  - Amount of time to implement trial in general
  - Time required by investigator to support trial and staff
  - Amount of time required by staff to support trial
  - Amount of time required to prepare for trial setup

- Burden of data and safety reporting
  - Amount
  - Method
  - Frequency

- Time to lead trial takes away from other necessary activities
  - Long work hours
  - Unpredictable work hours
  - Trial time makes it difficult to devote time to:
    - Clinical and non-clinical activities
    - Activities fostering academic promotion

- Dissatisfaction with trial finance
  - Sponsor/site contract negotiations
  - Sponsor/site budget negotiations
  - Final contract
  - Final site budget
  - Schedule of site payments

This will now be explored with experienced investigators in interviews

Interviews with experienced investigators almost done
Expert meeting in Spring 2017
Recommendations Summer-Fall 2017
Mobile Clinical Trials Program
Issue

• Mobile technology has been used in a variety of ways, but it has yet to be widely incorporated into clinical trials
• Mobile technologies offer the potential to increase the quality and efficiency of clinical trials
  • Reducing the burden of participation for research volunteers
  • Creating opportunities to develop novel endpoints
Mobile Clinical Trials Program

• PURPOSE:
Develop evidence-based recommendations that affect the widespread adoption and use of mobile technology in clinical trials

• ANTICIPATED IMPACT:
Increased number of clinical trials successfully leveraging mobile technology

4 PROJECTS

- Legal & Regulatory Issues
- Novel Endpoints
- Mobile Devices
- Stakeholder Perceptions
Issue recommendations related to

• Overcoming barriers to the use of mobile technology in clinical trials as perceived by key stakeholders

• Addressing legal and regulatory barriers that inhibit widespread use of mobile technology in clinical trials

• Identifying pathways by which to validate and qualify novel endpoints for clinical trials from data generated using mobile technology

• Characterizing the scientific and technological challenges inhibiting the widespread use of mobile devices in clinical trials
CTTI’s mission is to improve efficiency and quality in clinical trials

Let us know if you’d like to be involved

Thank You

www.CTTI-clinicaltrials.org

@ctti-clinicaltrials
Patient Diversity Awareness and Implementation for Research Sites

Mark Travers
Global Head, Monitoring Excellence
Merck
Population Under 18 Years and 65 Years and Over: 1990 to 2060

The population 65 years and over is projected to become larger than the population under 18 years in 2056.

Dashed lines represent population estimates for 1990 - 2011.
Projections of the Percent Minority 2012 to 2060

Percent of total population

The minority population is projected to become the numerical majority in 2043.
Historically, elderly women (in some therapeutic areas), and racial/ethnic minorities have been underrepresented in trials.

… particularly for women in some cardiovascular trials & general inclusion of black/African-American and minority participants in clinical trials.

Congress included Section 907 in the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012, giving FDA direction to evaluate this issue and take action.
Patient Diversity Awareness and Implementation for Research Sites

• Lead by SCRS in collaboration with multi-stakeholders
  – Focused on issues related to site’s knowledge and implementation challenges

• Gather empirical

• Provide training, tools & information to support site success
Diversity Project Partners

Seeking Other Visionaries
diana.foster@myscrs.org
Are You In?

Thank You
Site Payment Initiative

Co-Chairs

Clare Grace  
INC Research

David Vulcano  
HCA

Kelly Cummings  
Novartis
### Site in a Cash Crisis
Sites with 3 mos or less operating cash

<table>
<thead>
<tr>
<th>Site Revenue &amp; Less Than 3 Mos. Operating Cash</th>
<th>2014</th>
<th>2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;250K</td>
<td>65%</td>
<td>66%</td>
</tr>
<tr>
<td>251-500K</td>
<td></td>
<td></td>
</tr>
<tr>
<td>501K-1M</td>
<td>68%</td>
<td></td>
</tr>
<tr>
<td>1.1-1.6M</td>
<td></td>
<td>70%</td>
</tr>
<tr>
<td>1.7-2.1M</td>
<td></td>
<td>55%</td>
</tr>
<tr>
<td>2.2M +</td>
<td></td>
<td>36%</td>
</tr>
</tbody>
</table>
Site Payment Initiative

• SCRS multi-stakeholder initiative - 2016
  – Multi-year project
• Identify the point points
  – US initially
  – ROW to follow
• Identify executable solutions – for all parties
• Adoption
Site Payment Initiative Stakeholders
The Findings

1. Contract Terms: Payment Frequency
2. Contract Terms: Pay When Paid
3. Payment Back-Up Information
4. Hold Back Payments
5. Dispute Resolution
6. Study Subject Stipend Process
7. Invoice Practices
8. Screen Failures

2016-2017
Early Considerations

1. Payments within 30 days of data entry
2. Paid when paid in case of sponsor bankruptcy
3. Back-up information should accompany all payments
4. No hold-back; consider close out payment
5. Sharing by all parties of dispute resolution and escalation plan
Are You In?

Thank You
Site Study Dashboard

Co-Chairs

David Knepper  Tom Apostle  Mark Raupp
Allergan  Apostle Clinical Trials  QuntilesIMS
The Why

• FDA inspections continue to highlight reoccurring issues with site performance and increased incidents in similar findings over the past 10 years

• Sites can’t manage what they don’t know about
The Ask

SCRS Survey
- 76% of sites confirm they never receive feedback from sponsors or CROs on their study performance, except for recruitment metrics
- 79% of sites report a desire to receive a Site Study Dashboard
- 62% indicate receiving such feedback would definitely allow them to improve the quality from their site

Allergan Survey
- 85% Investigators who received a “Site Study Dashboard” from Allergan indicated the feedback was valuable
- 71% indicated the metrics were helpful or extremely helpful
- 100% indicated they used the data when received

Surveys: SCRS 2014, Allergan 2015
More Evidence is Not Needed – **Action Is!**

- Both bodies of knowledge indicate sites need and want concurrent feedback on their study performance and desire to change their behavior based on this feedback.

- SCRS is proud to have initiated this critical project and to have the collaboration of so many organizations committed to SCRS’ mission to ensure sites perform to the highest quality, which will create site sustainability.
Site Study Dashboard Initiative

Purpose
The creation of standard metrics to be measured during a study to be shared with sites and a method of how the information should be shared.

Scope and Key Objectives
The work stream will create objectives to support the development of the initiative
• Suggest and provide examples of measurable metrics that would enhance site efficiencies and quality
• Establish the standards, acceptable deviations (when applicable), and recommendations for comparison against study activity
• Create a universal Site Study Dashboard template to be adopted by industry
• Contribute to industry’s adoption of the Site Study Dashboard project
Dashboard Working Group
What Sites Want to Know

- Timeliness of Query Resolution
- Query Rate
- Number of Days to Enter Data into EDC
- Major Deviations
- Eligibility Violations
- Time from Site Activation to First Subject First Visit
- Screen Failure Rate
- Retention Rate
- Number of Subjects Randomized

Dashboard Survey 2015
Considerations

• Shared with sites within 30 day of site activation & quarterly thereafter
  – It is recognized that some studies may vary and sponsors are encouraged to adopt the frequency as seen to be necessary to ensure ongoing meaningful dialogue

• Recommended the dashboard be shared directly with the Principle Investigator

• All site information de-identified
Next Steps

• Download White Paper
  – myscrs.org

• Adoption

• On-going Assessment

• Modifications as Necessary
Are You In?

Thank You
Introducing

CLEAR Co-Leaders

Dex Bilkic, Boehringer-Ingelheim (TC)
Deena Bernstein, QuintilesIMS
Today’s CTA Reality

- Average CTA negotiations time
  - Over 13 weeks to execute globally
  - 10+ weeks in the United States

- We’ve gotten worse since 2010
Melanoma Example

• Melanoma 1% of all skin cancer
  • Majority of skin cancer deaths
  • 10,000+ lives lost annually in the US from melanoma

• GOAL - CTA execution 13 weeks to 7 weeks

• Bring life-saving products to market 6 weeks earlier could potentially save 1,164 patients suffering from melanoma in just the US
TJ Video
CLEAR Sustainability

SCRS Initiative

ACRO Supported

TransCelerate Supported
• CLEAR Charter Formed August 2014
• All Industry Stakeholders Represented
• Charter Members
  • SCRS Sites
    • All types
  • ACRO Members
  • TransCelerate Members
  • CROs – Non ACRO Members
  • Sponsors – Non TransCelerate Members
Thank You For Your Participation & Commitment
Rules of Charter Engagement

• The current CTA negotiation model is not sustainable
• Initial focus North America (US and Canada), will evaluate other countries later
• Remember the patients – get CTA’s executed so trials can start
• Focus on the absolute must-have language
• **Negotiation on principles, not positions**
• A level of compromise is required by all parties
• Not the end-all a living document – future iterations expected
• Not a Model CTA
• **Clauses That Matter**
  1. Confidentiality
  2. Indemnification
  3. Intellectual Property
  4. Publication Rights
  5. Study Subject Injury
• Referenced
  • START & ACTA
• Definitions
• Adoption & Refinement
Get Started with Clear Today!

- Download CLEAR on SCRS Website
  Myscrs.org
- View Clauses
- Review Definitions
- Cut and Paste in CTA
- Talk About it in Negotiations
Are You In?

Thank You
Clinical Trial Awareness Project

Todd Albin, MBA, CCRP
Senior Director, Site Enrollment Optimization
Acurian, Inc.
Global Clinical Trial Awareness Continues to be a Challenge

General knowledge about clinical research
Percent rate their general knowledge ‘Not at all informed’ and ‘Not very informed’

- **Not very informed**
- **Not at all informed**

<table>
<thead>
<tr>
<th>Region</th>
<th>Not very informed</th>
<th>Not at all informed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>17%</td>
<td>2%</td>
</tr>
<tr>
<td>North America</td>
<td>12%</td>
<td>2%</td>
</tr>
<tr>
<td>South America</td>
<td>18%</td>
<td>2%</td>
</tr>
<tr>
<td>Europe</td>
<td>27%</td>
<td>4%</td>
</tr>
<tr>
<td>Asia-Pacific</td>
<td>18%</td>
<td>3%</td>
</tr>
</tbody>
</table>

Base: All Respondents (n=12,009), North America (n=6,665), South America (n=877), Europe (n=2,618), Asia Pacific (n=1,302)

Source: CISCRP 2015 Perceptions & Insights Study
Video – Patient Speaking
• SCRS and Acurian have collaborated on the production of a global clinical trial awareness public service video with participant testimonials
• The video will be made available to sites throughout the world at no cost
• Translated versions will be produced with local language voice-overs and captioning

• www.WhyParticipate.com will be launched as a global resource for clinical trial opportunities and information
• Sites are encouraged to utilize this video on their Facebook pages, Web sites, waiting room TVs, etc.
• A shorter version for use in paid TV advertisements will also be made available
Together, Let’s Raise the Awareness of Clinical Research
Are You In?

Thank You