

October 14, 2018
SCRS Global Impact Partner Meeting
Global Site Solutions Summit

Facilitator: Sean Soth, Vice President, Global Business Partnerships

<u>Meeting Purpose:</u> The origin and evolution of the Global Impact Partner (GIP) program was shared. The primary objectives of the SCRS GIP program are to discuss industry challenges and opportunities that inform both GIP member companies and SCRS strategy, direction, projects and resources. The attending GIP representatives were asked to respond to a quick survey outlining organizational and site-facing priorities. The SCRS team coupled this with SCRS Leadership Council feedback from our June 2018 meeting in Annapolis to help develop the agenda.

<u>The format:</u> Small group discussions were built into the meeting, followed by sharing on the topics of highest importance to our GIP constituents. The "team topic" were:

- 1. Going Global
- 2. Contracts
- 3. Patient Recruitment
- 4. Site/Industry Relationships
- 5. Education/Training
- 6. Unpack SCRS

Each attending GIP representative selected a team topic to participate in along with an SCRS Leadership Council representative. An SCRS staff facilitator shared and reviewed a team topic worksheet to help guide the discussion. A representative from each team shared discussion highlights and chose a topic priority for SCRS to incorporate into programming throughout the upcoming year, and their team's suggested GIP theme for 2019.

<u>Post Meeting:</u> A summary of the activity is below. SCRS will provide an update on progress during the next GIP virtual call.

10-14-18

Welcome and opening: Sean Soth outlined the program and the plans for the day.

Why GIP

- Site success impacts everyone in research. SCRS is improving the way we bring it all together by engaging sponsors, CROs and solution providers to share insight on how to bridge gaps in site-facing challenges.
- SCRS Leadership Council: A brief overview of the SCRS Leadership Council
 was shared, including site members and Eagle Award winners. ACRO and
 TransCelerate joined the group as non-voting members with a seat in the
 Leadership Council.
- GIP theme: SCRS would like a shared GIP theme for 2019.
- Sean Soth shared how GIPs gain involvement in ongoing SCRS initiatives and programs, and described how two programs (Oncology and Ambassador Program) were built from ideas shared at previous GIP meetings. Sean invited Archana Sah and Dan Milam to present the background of the SCRS Oncology and Ambassador Programs.

<u>SCRS Oncology Program:</u> Archana Sah MS (Pharm.), PMP | Therapeutic Area Leader, Oncology | Genentech and Chair of the 2019 Oncology Site Solutions Summit

- Archana shared the early progress of the SCRS Oncology Program and why it became a focus for the organization in 2018. Early steps have evolved from an initial GIP request to include a discovery meeting, advisory group formation and a program launch meeting held in April 2018. These steps have provided action around 3 target areas for SCRS: 1) member engagement, 2) education, and 3) the inaugural 2019 Global Oncology Site Solutions Summit. Each of these target areas will inform SCRS Oncology programming into 2019, and will involve our advisory board.
- A short overview of the 2019 Global Oncology Site Solutions Summit was part of the discussion and it was shared that GIP organizations each had a complimentary registration to attend.

SCRS Ambassador Program: Dan Milam, Vice President, Global Engagement

 Dan shared the evolution of the Ambassador Program from GIP interest to the creation of the Program which offers in-country member engagement, scholarships, and one-day symposiums. In 2018 these activities were carried out in Hungary, Poland, Taiwan and South Korea. The program is sponsored by several GIPs including Acurian, Syneos and Lilly, whose support helps to increase membership engagement. The program yielded more than 300 member sites in these regions.

Team topics

- 1. Going Global:
 - a. Firestarter: SCRS continues to grow globally through OUS Summits, and Ambassador Program symposiums. Membership is up in these areas, but engagement requires maximum output and in-country resources. How does SCRS grow and engage globally, where should we be investing the most time, and how do we make the programs sustainable with our GIPs?
 - i. NOTES and SUGGESTIONS:
 - 1. Existing symposiums and ambassador work: funding model is least sustainable from the site prospective
 - 2. Determine how the members and sites can contribute.
 - 3. Create Ambassador 5013c, more as a foundation strategy.
 - 4. Sites may be concerned about joining with one company logo on it because it could be conceived as preferred treatment.
 - 5. Different countries have different rules, opens up things in the ecosystem (ie. non-profits, educational institutions).
 - 6. From sites provide more sustainable education for sites.
 - 7. From SCRS contribution high, tiering contribution, everyone plays equal role different mechanisms to join.
 - 8. All countries and all different players in the ecosystem.
 - Going global still focus on as a GIP YES.

GOING GLOBAL SUGGESTED GIP THEME - expanding capabilities

2. Unpack SCRS

- a. Firestarter: During the Site Landscape presentation at the Summit, we learned that some members use SCRS materials during the feasibility and selection process. We also believe that SCRS can equip industry (GIP and non-GIP) with fundamental ideas that showcase the value of the SCRS community. What would your organization find useful to share SCRS?
 - i. NOTES AND SUGGESTIONS:
 - 1. Provide more executive-level materials to share value, materials, with their company.
 - 2. Need approval for funding, materials would help make the case easier for executive-level.
 - 3. Explaining what is a GIP via video or brochure.

- 4. How can sites/partners understand what being a GIP means time, financial, resources to commit, why is it important to the industry, what they contribute.
- Quarterly newsletter training, whitepapers, articles...
 CROs and sponsors send out to their teams but more relevant content specific to site relationships with sponsors and CROs.
- 6. Need for sites to have education business management, wanting to be successful and improve enrollment but not running the business well.
- 7. Pillars of SCRS mentoring: develop this into something more formal where sites sign up as "needing a mentor", and can then be connected with the desired support and mentorship.
- 8. New generation of clinical research investigators
- 9. Advocacy/Mentorship what separates us?
- 10. Newsletter page to suggest teammates from your organization to sign up for newsletter.

UNPACK SCRS SUGGESTED GIP THEME – committed partners taking it to the next level, not afraid of commitment

- 3. Patient enrollment
 - a. Firestarter: This is a topic SCRS audiences of all shapes and sizes are continually interested in. Focus on diverse patient enrollment, socioeconomic barriers, new engagement options, data and tech are all elements of this topic. How can SCRS continue to develop the right information and opportunities for our audiences to learn together?
 - i. NOTES AND SUGGESTIONS:
 - Raising awareness of clinical research in school grad school, what's involved? How to do research. Changing syllabus – pull the people together from SCRS who are already doing that – medical school, rotation.
 - 2. Recruitment changing strategies, bring new strategies to the sites to implement? Track at the Summit?
 - 3. Webinar data analytics. How to analyze the data SCRS is already collecting.
 - 4. Webinar series are open to everyone, not just members or GIPs; but could be open to all industry groups or even patient populations.

5. Are tracks easier to consume? Patient engagement track?

Just labels – don't have to follow the track but just a label so you don't miss two at the same time of the same topic.

PATIENT ENROLLMEN SUGGESTED GIP THEME- the value of research and awareness of clinical research

4. Training

- a. Firestarter: Is training broken? Are sponsors and CROs training sitefacing teams the best way? How can we address disconnects in the delivery of training requirements at the site level and how can sites help sponsors/CROs understand where efficiencies can be gleamed?
 - i. NOTES AND SUGGESTIONS:
 - 1. Little bit of progress with TransCelerete with slow adoption into field, overall, much slower and nowhere near where it needs to be.
 - 2. Training acceptance we've already solved the problem, but we haven't implemented it.
 - 3. More awareness for pharma and CRO executives, but CRAs have not been sharing TransCelerate's message.
 - 4. Site initiation cut short because everyone is already being trained.
 - Industry has solutions and first steps, but to people in the field it has not become part of the CRO culture or world.
 TransCelerate is the first step and needs to be accepted
 - 6. Standardize other areas.
 - 7. How do we help spread TransCelerate's message? Does SCRS need to be the voice that shares this with sites? Does the CRO know what TransCelerate is and how their work impacts sites? If not, they're just going to use their standard process.
 - 8. Training our sites what are all the other people in the sites doing? Better strategy for training the whole staff
 - 9. Never a pharmacist investigator needs to be present and have their training recorded in order to train sites.
 - 10. Use technology effectively to make sure the training gets done.

TRAINING SUGGESTED GIP THEME - unity

5. Relationships

a. Firestarter: The human element of communication is consistently brought up in gap analysis at all levels: Sponsor-CRO-Site-Patient-solution

provider. Focusing today on the industry to site to solution provider gap – where can SCRS help develop best practices for all constituents as it pertains to better communication with sites?

- i. NOTES AND SUGGESTIONS:
 - 1. Building effective communication for trust and relationships.
 - Help sites understand key points of contact (if CRA can't
 answer the questions or they can't get in touch with whoever
 they need to). What questions do sites need to ask and
 where do they go to get that info? Info sheet or road map
 would be helpful.
 - 3. Show people good relationships spotlight success stories, celebrate best practices. Talk about great relationships that have been built and lead to real success testimonials.
 - 4. Create content program buddy talk for 10 minutes on a great story?

RELATIONSHIPS SUGGESTED GIP THEME – Working together, enhancing communication and relationships

- 6. Contracts
 - a. Firestarter: Clinical trial agreements take too long to execute. SCRS has developed CLEAR as an initiative, but the challenges include site awareness and industry acceptance. How can we gain momentum in industry and address risk perceptions at the same time?
 - i. NOTES AND SUGGESTIONS:
 - 1. Contracts take too long. Focus on the language, but it could go quicker.
 - 2. Coming to common language to agree with. Bring awareness to CLEAR.
 - 3. Process elongated language contributes. Define who should be there and agree on those personnel.
 - 4. Pivot on process.
 - 5. More education on the process, get together those individuals, sponsors sharing metrics – how long did it take some of the other sites/cros? How many times did they change it?
 - 6. Start with CLEAR, then come to the middle.

CONTRACTS SUGGESTED GIP THEME – make research great again