



SCRS SITES NOW →

Get to Know the Sites *NOW* Program



Virtual Site
Solutions Summit



Monthly
Sites Now Meeting



Quarterly
Sites NOW Forum



Monthly article in
SCRS Newsletter



Sites NOW
Playbook for Site
Success



Quarterly article
in SCRS
InSite Journal



Presentation of
findings at 2021
SCRS Summits

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2021 Horizon



Global Oncology Site Solutions Summit February 16-18, 2021 VIRTUAL	European Site Solutions Summit April 2021 VIRTUAL	Asia / Australia / New Zealand Site Solutions Summit July 14-16, 2021 Hybrid of Virtual
ANTICIPATED ATTENDEES 500	ANTICIPATED ATTENDEES 400	ANTICIPATED ATTENDEES 400

Join the SCRS community on this exclusive digital experience! Lead and engage a remarkable audience of sites, sponsors, CROs and solution providers.

VIRTUAL SUMMIT SPONSORSHIP

Inbox Visibility

- Included on all promotion emails as sponsor (up to 4 total)
- Included on Post-Conference Sponsor Thank You email (on email to all membership, includes logo)

Event Exclusivity

- Access to Virtual Summit attendee mailing list (name, organization, title, mailing address)
- (4) full conference registrations
- Logo included on event webpage

Profile Perfection

- Schedule 1:1 meetings with attendees
- Add relevant content including videos, documents and social posts to your company profile
- Post updates to the conference Social Feed inviting attendees to interact with your content



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FEB 16-18, 2021



Global Oncology
Site Solutions Summit
PARTNERING FOR SUCCESS



Site Solutions Summit
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List current as of 26 October 2020

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PRE-SITE



as of 16 Nov 2020

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Ground Rules



Agenda:

- 11:30-12:15 Intro and main presentation
- 12:15-1:00 Coffee Break Meet-ups and Team Breakouts
- 1:00-1:30 Team reporting in main room
- Next Sites NOW (January 26 11:30, Patient Recruitment)

SCRS Sites NOW: Diversity in Clinical Trials



Speaker:

Diana Foster

**Vice President Strategy and
Special Projects**

SCRS

December 15, 2020



SCRS

DIVERSITY



Supporting Sponsors



Contributors



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SCRS SitesNOW – Diversity in Clinical Trials

Diana Foster, Ph.D.
Vice President, Strategy and Special Projects, SCRS

December 15, 2020



The Importance of Diversity Inclusion and Equity Now and in the Future

- Regulatory Perspective
- Sponsor Requirements
- Changing Populations/ Demographics/ Culture
- Establishing Knowledge and Best Practices
- Assessment and Evaluation of Sites Changes in Perception and Behaviors Regarding Diversity



Diverse patient populations have different responses to certain pharmaceuticals and ignoring this poses a significant community and global health risk.

FDA Office of Minority Health and Health Equity (OMHHE)

Mission

To promote and protect the health of diverse populations through research and communication that addresses health disparities.

Vision

To create a world where health equity is a reality for all.



FDA Guidance on Diversity

June 2019

Despite FDA policy initiatives focused on promoting enrollment practices that are more *inclusive*, certain groups continue to be underrepresented in clinical trials. Efforts geared towards making trial populations match those most likely to use the drug if approved, could still be improved

How can this be achieved?

1. Broadening eligibility criteria
 - a. Assess age, gender, concomitant illnesses
2. Sponsors should adopt practices for determining eligibility criteria that will allow the clinical trial population to *reflect the diversity* of the patients who will be using the drug if the drug is approved by *decreasing common burdens/ potential challenges*
 - a. Frequent visits
 - b. Travel Costs
 - c. Missed work
 - d. Interference with Family Obligations (child/elder care)
 - e. Financial burdens

Equity in Clinical Trials- Sponsors Role

- Responsibility to ensure that our clinical trial participants reflect the racial and ethnic diversity countries where clinical trials are conducted, and the epidemiology of the diseases intended to treat or prevent
- In order to increase equity and address healthcare disparities Sponsors should...
 - Recognize the importance of **cross collaboration** with industry partners
 - **LISTEN** to the voice of our patients, advocacy partners and sites
 - Apply **insights** to our clinical development plans
 - Understand the **barriers to entry** that our underserved communities face and identify solutions to remove them
 - Ensure patient facing materials are easily understood and **culturally sensitive**
 - **Invest** in opportunities that will increase our **diverse clinical workforce** of the future
 - **Partner** with multicultural partners to foster community outreach, awareness and education
 - Be **transparent** with our site partners on our diverse recruitment goals, and what success looks like
 - **LISTEN** to what our sites need to ensure success

Equity in Clinical Trials- Your Role as a Site Partner

As a Site Partner, you have the very important responsibility of providing high quality care and safety oversight to patients while compliantly conducting a clinical trial and meeting administrative demands

- **Know the possibility for diverse recruitment**
 - Does your site have all the tools necessary to support diverse recruitment?
 - Does your site serve a diverse patient population?
- **Request the support you need...early**
 - Does your site need additional resources from the Sponsor to reach the goal?
- **Connect with the surrounding community**
 - Does your site have relationships within the community? Can you develop these relationships?
- **Set up for success**
 - Invite everyone to participate, as appropriate
 - Allow adequate time for explanation and consenting

The SCRS Diversity Project

To Support Site Sustainability in Regard to Building Knowledge
and Ability to Execute in Enrolling Diverse Populations in Clinical Trials

Diversity Awareness Program Launched

- Merck/SCRS discussed the creation of a diversity program aimed at supporting the clinical research site
- The diversity awareness program was launched in 2016
- In the coming years, several organizations joined forces with SCRS and Merck to support this critical industry initiative

Diversity Awareness Program Supporters

Supporting Sponsors



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Purpose of the Diversity Site Assessment Tool (DSAT) Published Paper

- To report on internal consistency reliability and construct validity of the Diversity Site Assessment Tool (DSAT), a self-assessment instrument designed to self-report the extent to which best practices related to recruitment of diverse patient populations during clinical trials are used. After reliability and validity are demonstrated, clinical trial sites will be able to diagnose areas of best practices that their own site can improve upon.



Development of the Diversity Assessment Tool (DSAT)

- Step 1: Gathered a group of content experts in 2017 to address the development of the items to be evaluated within the DSAT instrument
 - *Published Paper: Patient Diversity Awareness: Developing a Better Understanding of the Knowledge, Expertise and Best Practices at Clinical Research Sites to Meet the Needs of an Increasingly Diverse United States Population, September 2017*
- Step 2: Conducted a pilot study that consisted of interviews and completed surveys among sites to evaluate the validity of the initial list of items to be assessed by the instrument
 - *Published Paper: Recruiting Diverse Patient Populations in Clinical Studies: Factors That Drive Site Success, July 2018*

Launch of the Diversity Assessment Tool (DSAT)

- Step 3: Based on feedback received from the pilot study, content experts re-evaluated and revised the tool
 - *Published Paper: Diversity in Clinical Studies: A Pilot Study to Examine the Validity and Reliability of a Site Assessment Checklist for the Evaluation of Best Practices in Recruiting Diverse Patient Populations for Clinical Trials, July 2020*
- Step 4: A final paper was published and released in the *Mediterranean BioMedical Journals, Integrative Journal of Medical Sciences*, 2020, Volume 7, ID 266, October 2020
 - All rights reserved and copyright will be held by SCRS

Launch of the Diversity Assessment Tool (DSAT)

- *The Diversity Site Assessment Tool (DSAT), Reliability and Validity of the Industry Gold Standard for Establishing Investigator Site Ranking* article will be released on SCRS' website the week of October 19, 2020
 - Other marketing activities are being developed by a sub-committee of the diversity work group, which Parexel's own Brandon Doyle is contributing to this effort
- The DSAT tool is assessable through the SCRS website (www.myscrs.org) or by linking this link: <https://myscrs.org/learning-campus/diversity-in-clinical-trials/>

**Allows sites a
chance for ranking
score to be shared
internally or
externally**



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2020 and Beyond

Moving the Needle – The Future Direction of the Diversity Project



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The future will bring ongoing questions of significance that will directly impact the clinical research site. The element of demographics, government and sponsor expectations, will become of even greater importance to sites as diverse populations expand



Call for Site Contributors to the SCRS Diversity Program

Diana Foster, Ph.D.
diana.foster@myscrs.org
214.263.1094



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BREAKOUT TALKING POINTS:

1. Where have you seen success in increasing the enrollment of diverse patient populations in clinical trials?
 - a. In other words, what sort of things have you seen or have implemented onto a trial to increase diversity?
2. Where do you see the future of diverse patient recruitment and enrollment?
What innovations on the horizon do you feel will help diversity and how?
3. How do you see or have seen decentralization of clinical trials impacting diverse patient recruitment?