Moving the Needle

ACRO toolkit to advance decentralized clinical trial technology

November 10, 2021 at 12-1pm ET

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Moderator: Ari Feldman
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But first, housekeeping

• Please note: **today’s session is being recorded**
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Agenda

- ACRO DCT WP
- Toolkit Components
- ACRO DCT WP Meetings & Listening Sessions
- Regulatory DCT Progress
ACRO DCT WP- Mission

The ACRO Decentralized Clinical Trials Working Party was established in 2019 for ACRO member experts to complete specific deliverables – and to share these tools with regulators, sponsors, and stakeholders – in order to support and advance the adoption of decentralized trials.
ACRO DCT Toolkit Components

The DCT Toolkit is now available on ACRO’s website and contains four resources:

- Bringing the Trial to the Patient: A Quality-by-Design Manual for Decentralized Clinical Trials
- Decentralized Clinical Trials Risk Assessment Considerations
- Decentralized Clinical Trials Data Flow Maps
ACRO DCT Toolkit - White Paper

- Introduces the ACRO DCT Toolkit
- **Features experts** from UK MHRA and ACRO membership
- Includes **case studies** from ACRO members
ACRO DCT Toolkit - QbD Manual

A comprehensive quality-based framework dedicated to decentralized clinical trials – from early design and planning to close and archiving.
ACRO DCT Toolkit - Quick Reference Guide
ACRO DCT Toolkit - Risk Assessment Considerations

- **Template** to systematically raise questions that facilitate cross-functional discussion to **identify and mitigate potential risk** in decentralizing trial functions

- **Complements** a company’s existing risk tools
ACRO DCT Toolkit - Data Flow Maps
ACRO DCT WP Meetings and Listening Sessions
Regulatory DCT Progress

FDA Expected to Issue Draft Guidance on Decentralized Trials in 2021

April 29, 2021

Details of the FDA’s draft guidance on the operation of decentralized clinical trials due out this year are starting to emerge, with an expected emphasis on endpoint analysis, data quality and control, and the appropriate use of electronic informed consent.

Sarah Blankstein, an associate in the life sciences group at Dechert, will incorporate into that guidance some of the key considerations presented by a panel of experts at a recent webinar hosted by the International Harmonization Council (ICH).

At an FDA webinar last week on the FDA’s draft guidance, Blankstein said one of the main goals of the document is to provide a roadmap for sponsors on what practices will be acceptable as part of a decentralized trial. The guidance is expected to be finalized in the last quarter of 2021.

Other topics that may be addressed in the guidance include: the need to develop clear criteria for determining the location and number of sites; the design and implementation of centralized trial sites; and the process for ensuring data quality and data protection during the trial.

The guidance is intended to be a flexible framework that can be adapted by sponsors to fit the specific needs of their clinical trials.

Conclusions from the webinar panelists included:

- The need for clear definitions of what constitutes a decentralized trial.
- The importance of ensuring data quality and security throughout the trial.
- The potential benefits of decentralized trials for patient access, trial efficiency, and cost effectiveness.
- The need for ongoing monitoring and evaluation of decentralized trial practices.

The guidance is expected to be finalized in the last quarter of 2021.

Considerations for the Design and Conduct of Decentralized Clinical Trials: Regulatory Perspectives

Cheryl Grandinetti, Pharm.D.

Good Clinical Practice Assessment Branch, CDER/FDA

swissmedic

Decentralised clinical trials (DCTs) with medicinal products in Switzerland

(Version 1.0, 09 September 2021)

1. Introduction

1.1 Content and objectives of DCTs

1.2 Legal framework in Switzerland

2. DCT aspects

2.1 Recruitment through digital channels

2.2 Performance of trial-related interventions outside the trial site

2.3 Dispersing and administration/monitoring of the ITP outside the trial site

2.4 Data capture outside the trial site using mobile technologies

2.5 The question of CER certification of the technology employed

2.6 Remote source data verification

3. Summary and outlook

4. The Danish Medicines Agency’s guidance on the implementation of decentralized elements in clinical trials with medicinal products

5. Conclusion

6. References

7. Appendix

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9. Figure 1: Decentralisation overview
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THANK YOU!

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