DIGITAL MEDICINE SOCIETY

Moving the Needle

ACRO toolkit to advance decentralized clinical trial technology

November 10, 2021 at 12-1pm ET

Fiona Maini
Senior Director, Global Compliance and Strategy
Mediata, a Dassault Systèmes Company

Valeria Orlova
Regulatory Strategy Analyst
Mediata, a Dassault Systèmes Company

Moderator: Ari Feldman
Vice President, Global Compliance and Strategy
Mediata, a Dassault Systèmes Company

But first, housekeeping

- Please note: **today's session is being recorded**
    - Slides and recording will be available on DiMe's webinar page after the session
- To ask a question for discussion during live Q&A, please either:
    - **'Raise your hand'** in the Reactions and the moderator will unmute you to ask your question live, or
    - **Type your question** into the chat box

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Agenda

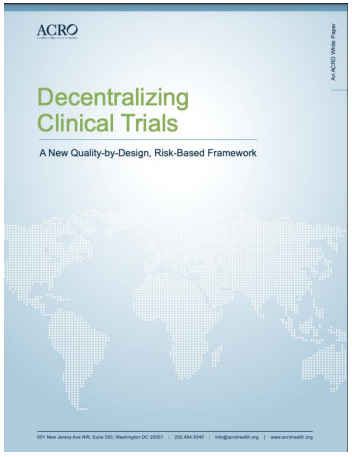
- ACRO DCT WP
- Toolkit Components
- ACRO DCT WP Meetings & Listening Sessions
- Regulatory DCT Progress

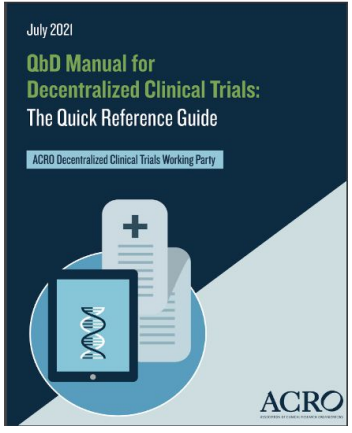
ACRO DCT WP- Mission

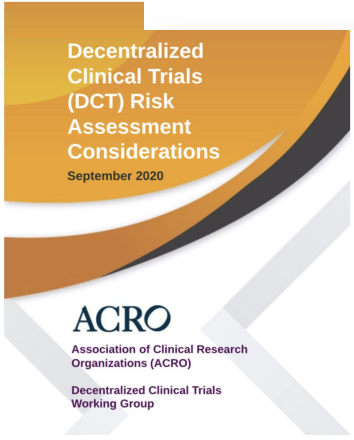
ACRO
ASSOCIATION OF CLINICAL RESEARCH ORGANIZATIONS

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





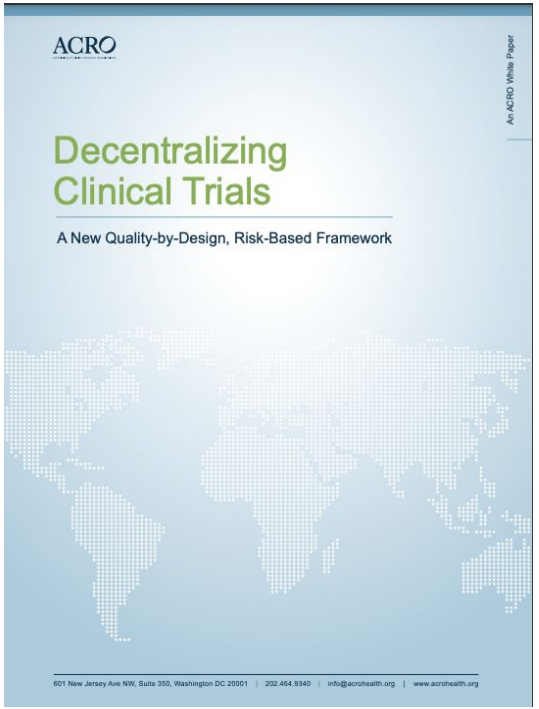


The DCT Toolkit is now available on ACRO's website and contains four resources:

- Bringing the Trial to the Patient: A Quality-by-Design Manual for Decentralized Clinical Trials
- Decentralized Clinical Trials Risk Assessment Considerations
- QbD Manual for Decentralized Clinical Trials: The Quick Reference Guide
- Decentralized Clinical Trials Data Flow Maps

ACRO DCT Toolkit - White Paper

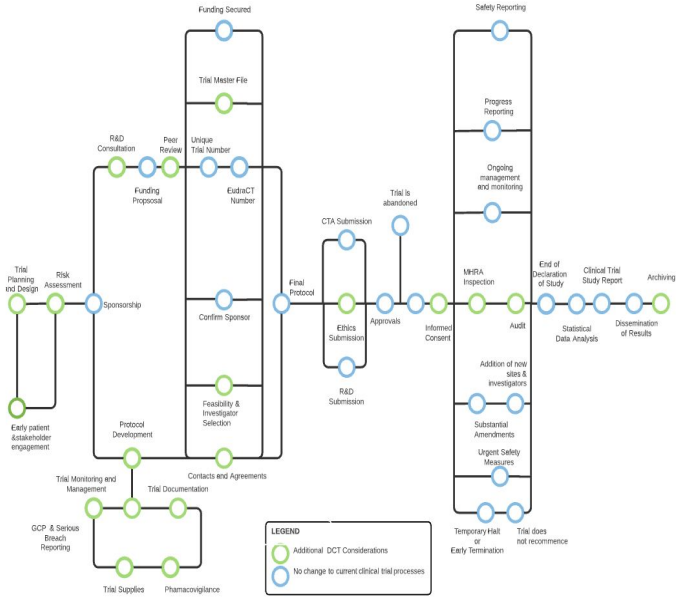
- Introduces the ACRO DCT **Toolkit**
- **Features experts** from UK MHRA and ACRO membership
- Includes **case studies** from ACRO members

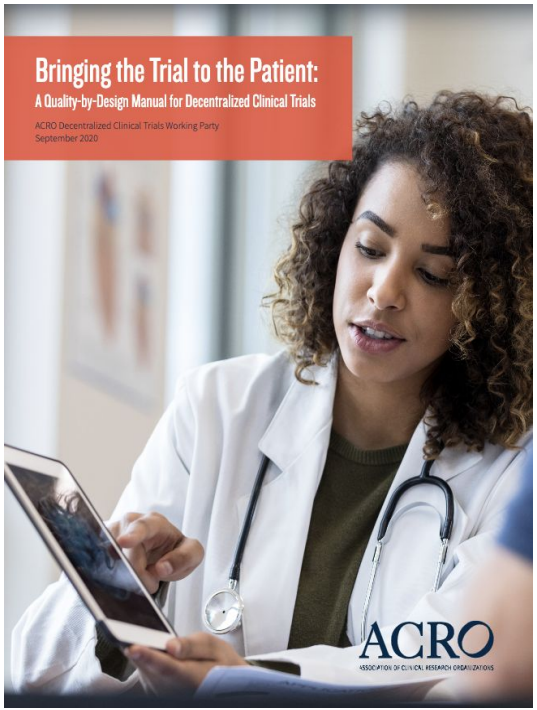


ACRO DCT Toolkit - QbD Manual

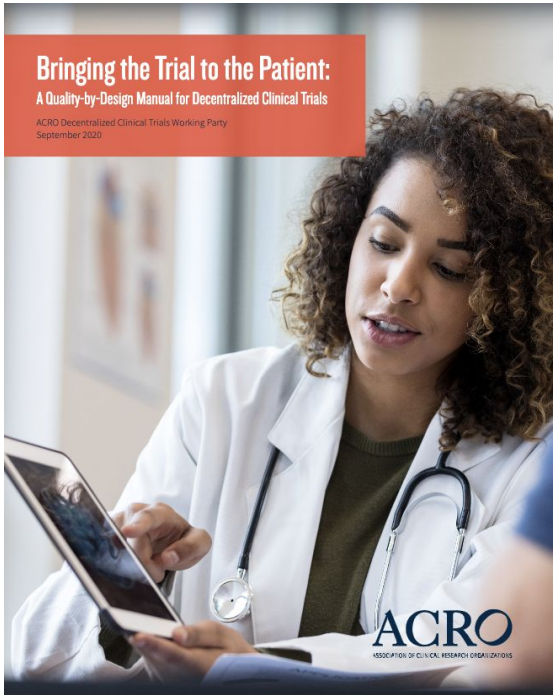
A comprehensive quality-based framework dedicated to decentralized clinical trials – **from early design and planning to close and archiving**

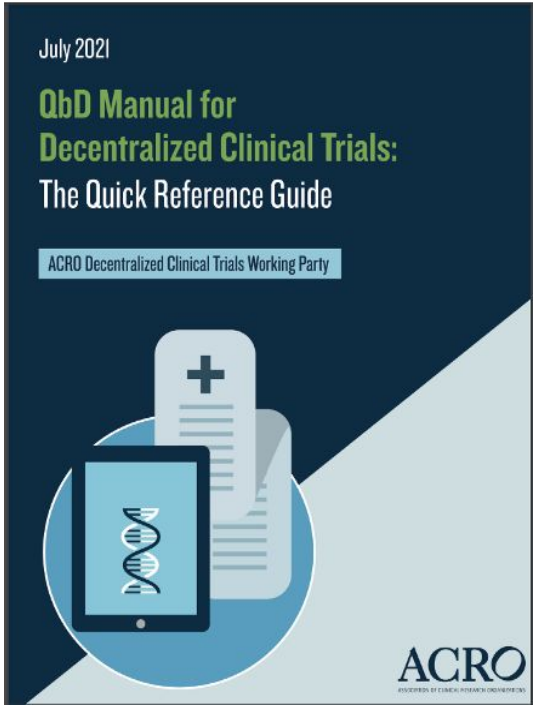
TOPRA Awards for Regulatory Excellence





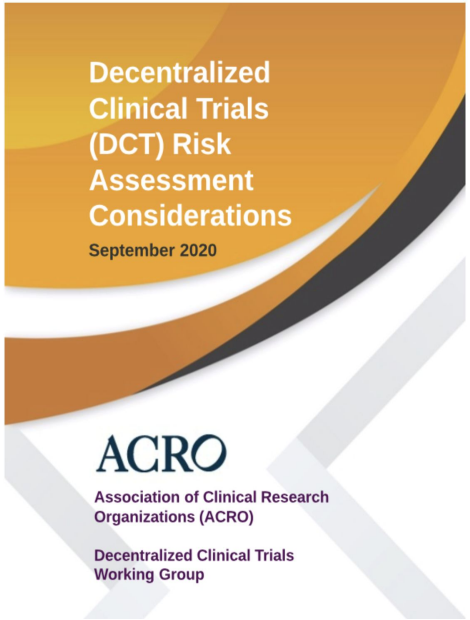
ACRO DCT Toolkit - Quick Reference Guide



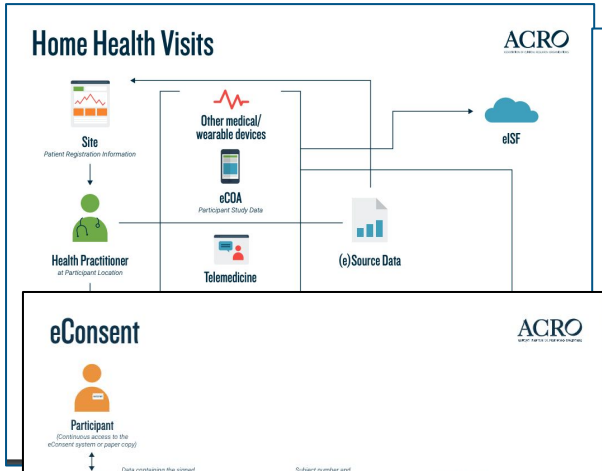


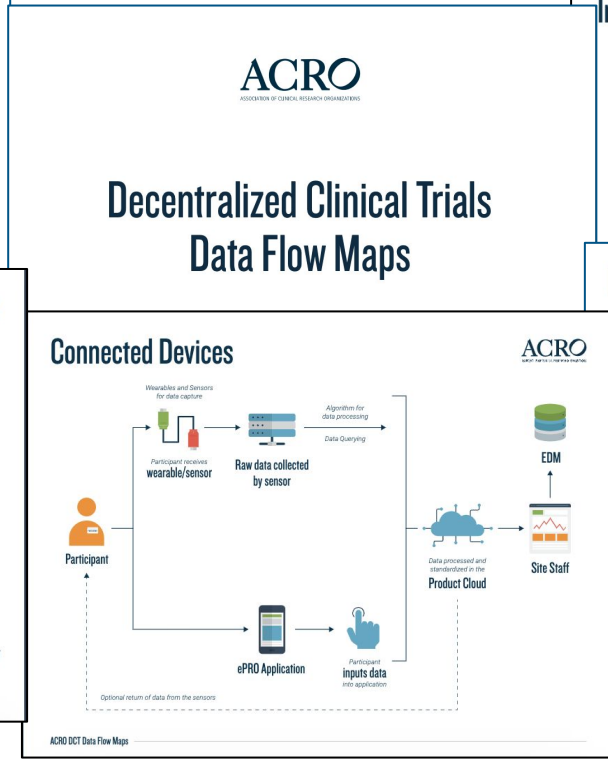
ACRO DCT Toolkit – Risk Assessment Considerations

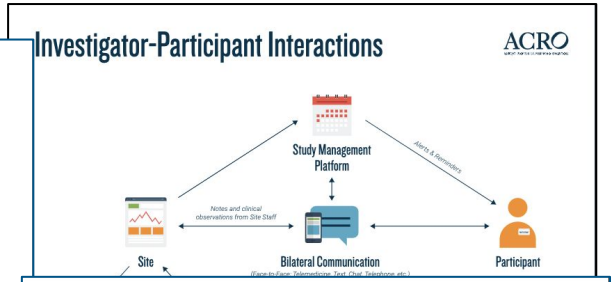
- **Template** to systematically raise questions that facilitate cross-functional discussion to **identify and mitigate potential risk** in decentralizing trial functions
- **Complements** a company's existing risk tools

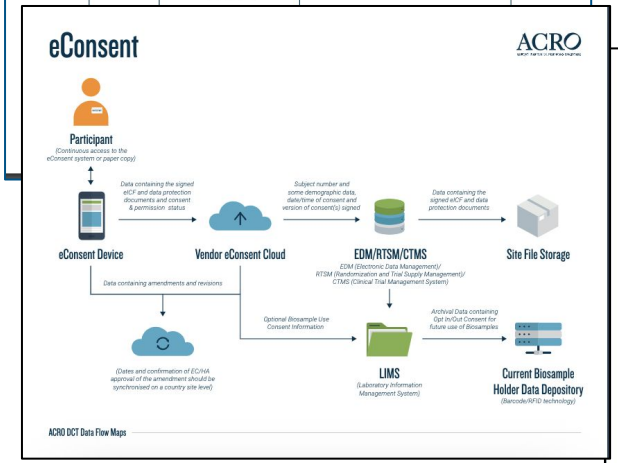


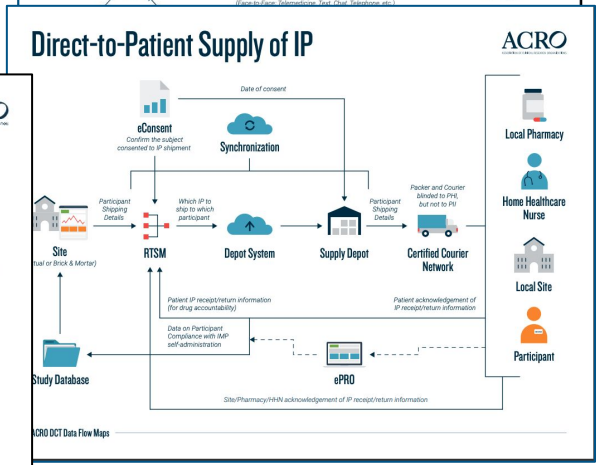
ACRO DCT Toolkit - Data Flow











ACRO DCT WP Meetings and Listening Sessions

Regulatory DCT Progress

MEDIDATA

350 Hudson Street
New York, NY 10014
United States
medidata.com

July 16, 2021

To:
The Honorable Diana DeGette
United States House of Representatives
2111 Rayburn House Office Building
Washington D.C. 20515

The Honorable Fred Upton
United States House of Representatives
2183 Rayburn House Office Building
Washington D.C. 20515

RE: Comments for the Honorable Diana DeGette and The Honorable Fred Upton in respon
Draft Bill "Cures 2.0 Act" (G:\M\17\DEGETT\DEGETT_019.XML).

Dear Representatives DeGette and Upton,

Medidata would like to thank you for issuing the 21st Century Cures 2.0 draft review. Cures 2.0
very patient focused and acknowledges the need to leverage data and technologies to advance
and clinical research for the benefits of patients and public health. We believe that the us
technologies and intelligently unlocking the power of data, new clinical and healthcare insight
derived that can facilitate decision making and in turn accelerate research and treatments to pat

FDA Expected to Issue Draft Guidance on Decentralized Trials in 2021

April 26, 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 conse

Sarah Blankstein, an associate in the life scie
to incorporate into that guidance some of the
of clinical trials during COVID-19, including re
statistical considerations presented by such

At an FDAnews webinar last week on the FDA
quality and control is "anticipated to be

Other topics that may be addressed in

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 10 June 2021
2 EMA/226170/2021
3 Good Clinical Practice Inspectors Working Group (GCP IWG)

4 **Guideline on computerised systems and electronic data in**
5 **clinical trials**
6 Draft

release for consultation	4 March 2021
n	18 June 2021
line for comments)	17 December 2021
t	TBC

flection paper on expectations for electronic source data and data
ta collection tools in clinical trials' (EMA/INS/GCP/454280/2010).

vided using this template. The completed comments form should be sent to
europa.eu

mputerised systems, electronic data, validation, qualification,
dit trail, user management, security, electronic clinical outcome

ICH
harmonisation for better health

19 April 2021

ICH-E6 Good Clinical Practice (GCP)

Explanatory Note

g timely technical
o the needs of the
n the development

rchers beyond the

MHRA

FDA

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

Cheryl Grandinetti, Pharm.D.

Good Clinical Practice Assessment Branch, CDER/FDA

Medicines & Healthcare products Regulatory Agency

FDA U.S. FOOD & DRUG ADMINISTRATION

swissmedic swissethics

Decentralised clinical trials (DCTs) with medicinal products in Switzerland

(Version 1.0, 09 September 2021)

1. Introduction

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

04 May 2021
Version 1.0
T +45 4488 9123
E kl@dkma.dk

The Danish Medicines Agency's guidance on the implementation of decentralised elements in clinical trials with medicinal products

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THANK YOU!

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