



DTRA
DECENTRALIZED TRIALS
&
RESEARCH ALLIANCE

All Hands Meeting

November 30, 2023



Agenda

- Welcome
- Annual Meeting Wrap-Up
- Initiative Change Management Practices
- Initiative Outputs
 - A new tool designed by Michelle Shogren



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Annual Meeting Wrap-Up

Jane Myles & Paige Altrogge



Annual Meeting Wrap Up

- Regulatory/Governmental Agency Perspectives
 - Paul Kluetz - FDA Deputy Director for Oncology
 - Demystified oncology trials being ready for DCTs
 - FDA, BARDA, ONC, NIH
 - Commitment to DCTs for support representation and resilience for the nation's research infrastructure
 - BARDA
 - Creating lasting clinical trial infrastructure including decentralization for emergency situations
 - EMA/FDA
 - Harmonization between EMA/FDA

Annual Meeting Wrap Up

- Global Adoption of DCTs
 - Does Global adoption have to be all or nothing?
- Site Adoption
 - Major topic at DCT Town Hall
 - DTRA + SCRS + ACRP alignment to create site support tools
- Investor State of the Market
 - More access to capital and raises in 2024
 - Not much change in valuation



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Change Management Initiative

Key Findings

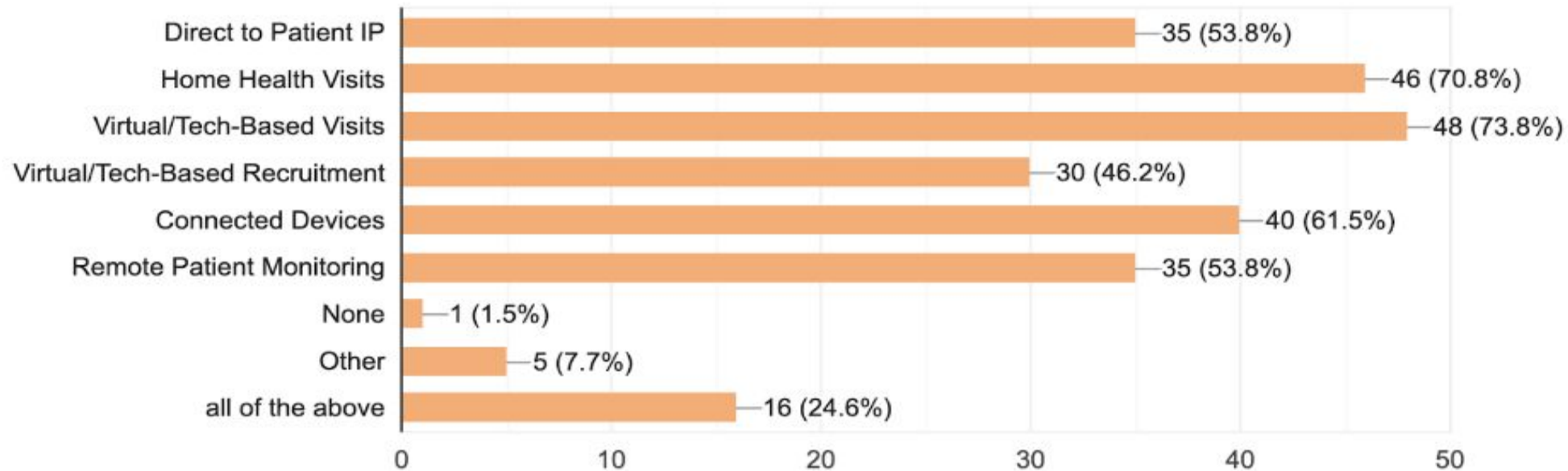
Jane Myles



Change Management Initiative: Key Findings

2.9 With which DCT components(s) do you have experience?

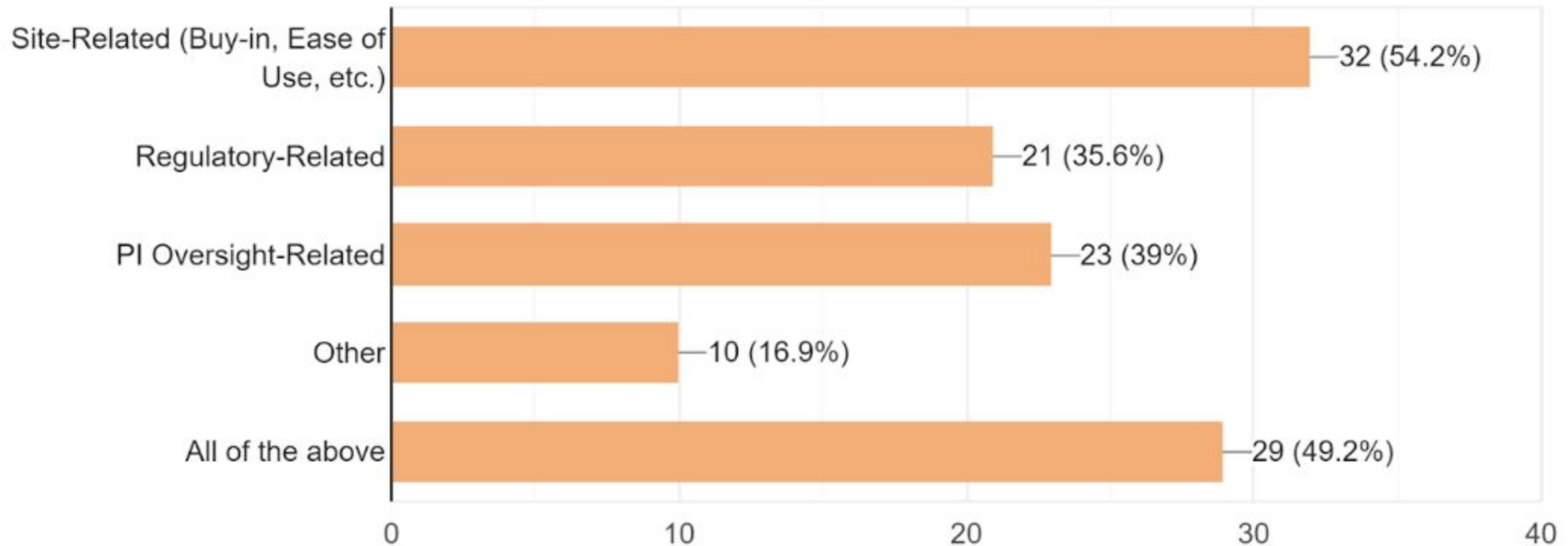
65 responses



Change Management Initiative: Key Findings

2.10 Which barriers with DCT have you faced/overcome?

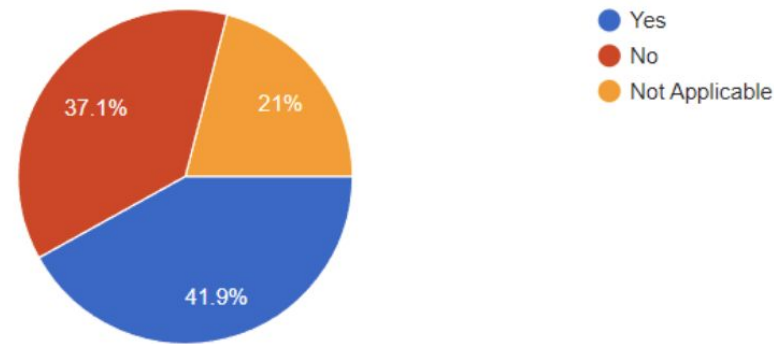
59 responses



Change Management Initiative: Key Findings

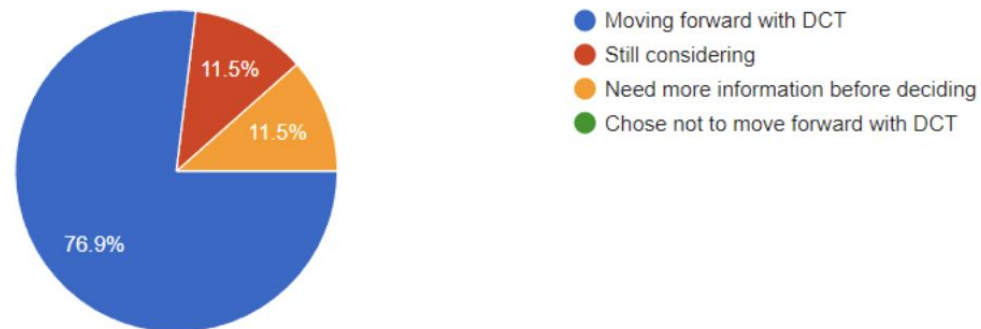
4.1 Have you had discussions with the FDA or your country's regulatory agency about decentralized components?

62 responses



What was the outcome of the discussion?

26 responses





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Change Management Tool: Prototype

Michelle Shogren

Change Management

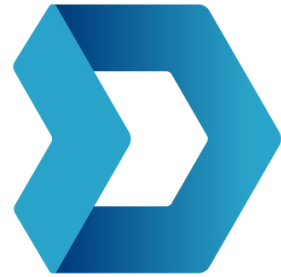
- What support do you have for change management in your team?
- Are there specific tools / methods you use?
 - What can you share?
- Is there anything missing from your toolkit?

Change Management

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Thank you for your time!

Happy Holidays and New Year! We'll see you in 2024



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