Designing a Medical Device Study under US FDA Requirements

LIVE

Webinar December 15th 2022
1:00pm ET / 10:00am PT

Stephanie Mull
Senior Director of Clinical Operations
PROXIMA CLINICAL RESEARCH

Páll Jóhannesson
Co-Founder and Managing Director
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Today's Speakers

Stephanie Mull
Senior Director of Clinical Operations

- 20+ years of clinical experience
- POW from sites, sponsors, and CROs10+ years of clinical experience

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Páll Jóhannesson
Co-Founder and Managing Director

- 10+ years of clinical experience
- Helped more than 100 companies collect high quality data

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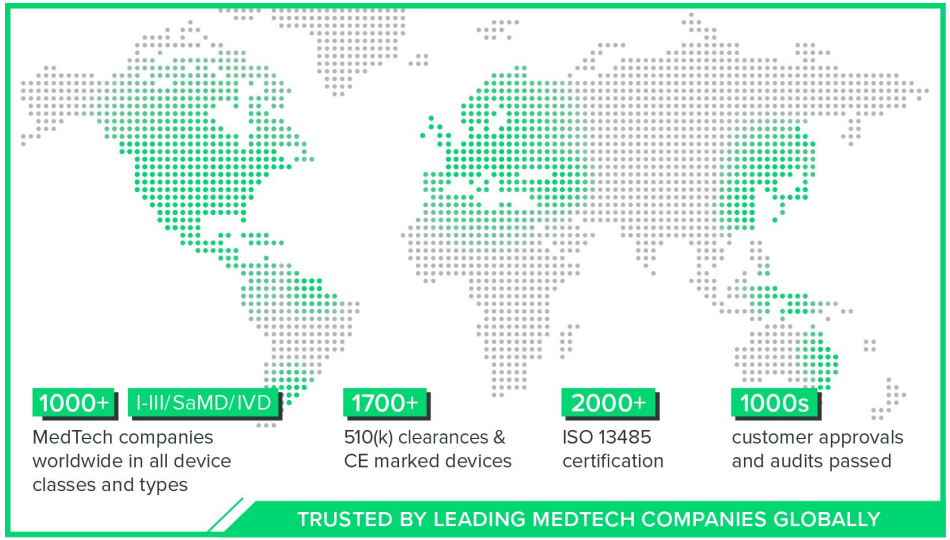
MEDICAL DEVICE QUALITY IS ALL WE DO, AND WE'RE ALWAYS AHEAD OF THE GAME.

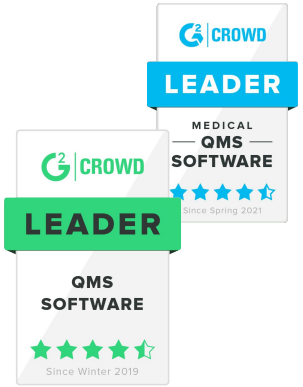
100+
years industry experience

522k
podcast listeners

200k+
look to us for the latest in quality

#1
blog and podcast in the industry





"Best eQMS I have ever used..."

This is the easiest eQMS I have used in the 20 years I have been in the Medical Device Industry. ***It is simple, intuitive and easy to use...*** We are successfully implementing a Quality Culture.

- Director of Regulatory Affairs & Quality Assurance

"Modern QMS Software and Outstanding Customer Service."

★★★★★

"Demystifying QMS and Regulatory Requirements"

★★★★★

"Makes your QMS Simple and Effective"

★★★★★

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What Is SMART-TRIAL?

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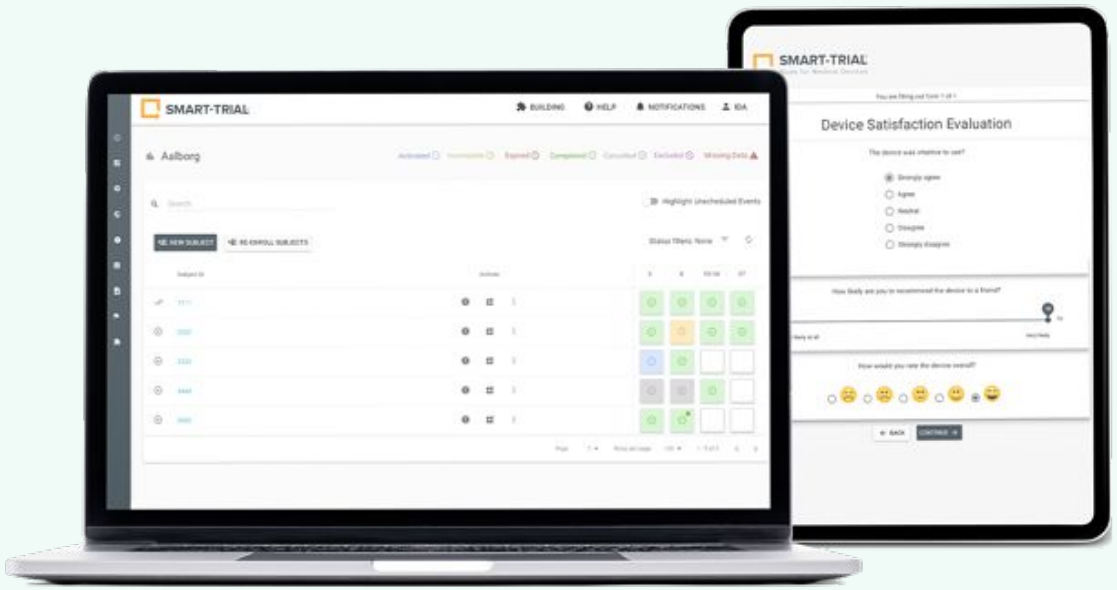

est. 2013

The First and Only Electronic Data Capture (EDC) system designed for MedTech

- Supported 400+ MedTech studies
- 100+ MedTech companies across 16 countries with sites all over the world
- Medical Device classes I, II(a&b), III and IVDs
- Clinical activities from pre- and post-market
- Customer audits from USA and EU authorities
- Customers completed clinical data submissions in N-America, EMEA, Oceania, and Asia

Who Is Proxima?

CRO Partner from A to Z

Proxima CRO provides regulatory, quality, and clinical research expertise to life sciences companies of all sizes and stages.

With headquarters in the Texas Medical Center (TMC), the largest medical center in the world, Proxima CRO guides hundreds of emerging medical device, pharmaceutical, biotechnology, and diagnostic companies in 17 countries across five continents to further advance the $130 billion market.

Contact us at www.ProximaCRO.com

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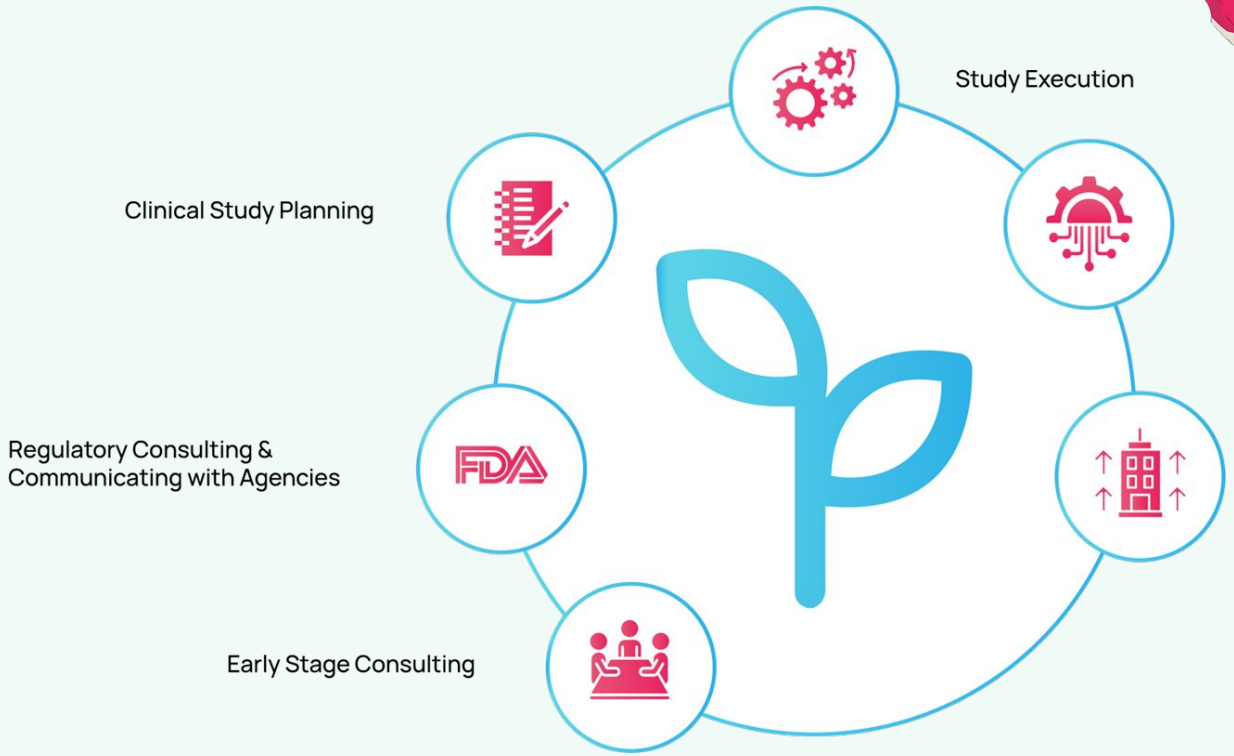

Today's Agenda

Avoiding Common Clinical Pitfalls

Optimizing Clinical Study Resources

Site Selection and Safety Management

Producing Higher Quality Clinical Evidence

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POLL #1

On your screen now

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Common Pitfalls in Clinical Studies

Starting on paper

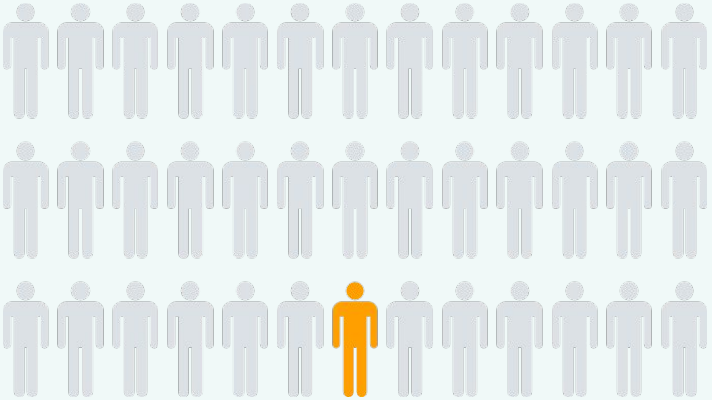
Go digital from the start

Too much data

- ➔ Overburdens clinical staff
- ➔ Increases complexity of operation an analysis
- ➔ Increases time and resources

Include ePRO/eCOA data

Forgetting the individual



Include ePRO/eCOA data

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Common Pitfalls in Clinical Studies

Relying too much on KOL

Go beyond clinical evidence

The Clinical workflow

- ➔ Good study design does not equal quality data
- ➔ Variation between sites & countries
- ➔ Missing and erroneous data, dropouts, and lack of motivation

Test and seek feedback

GCP and validation

- ➔ Choose validated solutions, e.g. IEC62304, PIC/S, & ISO13485
- ➔ Support compliance to ISO14155 (GCP), GDPR, FDA CFR21 Part11 etc.

Go with compliance!

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Resource Considerations

Evaluate your team structure and resourcing needs.

What skill sets does your team have in house and what might you need to obtain or outsource?

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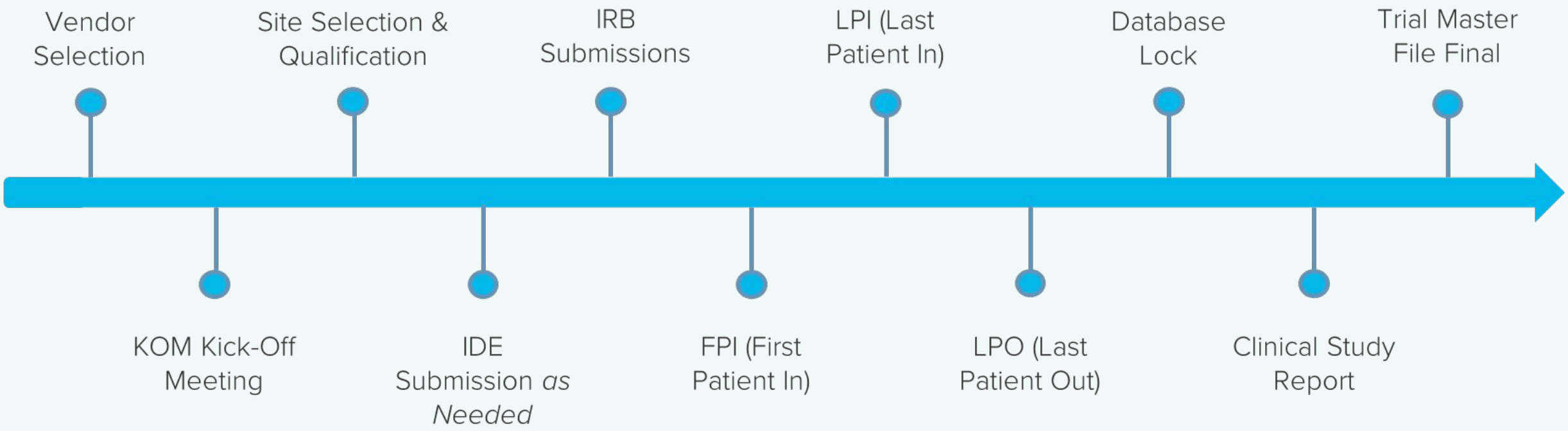
Project Timeline Considerations

Know your key deliverables and set your overall timeline



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Site Selection Considerations

Investigator enrollment

- Access to patient population
- Experience
- Competing studies
- Resources, time
- Investigator engagement

Site timelines & processes

- IRB/Ethics committee
- Scientific committees
- Site document procedures
- Contract & budget

Site commitment

- Don’t over commit to a single site
- Consider how many sites you need
- Consider both known thought leaders and known enrollers

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Safety Management Considerations

- → Know reporting requirements for SAEs and UADEs
- → Create a Safety Management Plan (SMP)
- → Consider using validated safety database
- → Consider use of a DSMB (Data Safety Monitoring Board)
- → CEC (Clinical Evaluation Committee) may be necessary for adjudication

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Risk Mitigation Strategy

Category	Question	Considerations
Patient Safety	Product related side effects?	Protocol-specific reporting requirements for AEs / SAEs / UADEs
Complexity	Complex procedure?	Risks for device/procedure issues Training needs
Subject Population	Critically ill? Difficult to diagnose?	SAEs / UADEs risks Centralized core labs or readers
Geography	Country specific SOC?	HA/EC approval risks

POLL #2

On your screen now

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Produce Higher Quality Clinical Evidence

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Produce Higher Quality Clinical Evidence

Test & Seek Feedback

- ➔ Analyze the workflow and differences
- ➔ Identify risks and how to mitigate them
- ➔ Test, test, and test, and seek feedback

Start at the End

- ➔ Hypothesis
- ➔ Statistical analysis plan
- ➔ Data collection plan
- ➔ Data collection

Use Purpose-built Tools

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Time for

Q&A

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