# How to Use Clinical Data in Medical Device Submissions in the EU & US

LIVE

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## Presenters

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# Overcome Common Pitfalls and Optimize Your Cross-Atlantic Clinical Strategy

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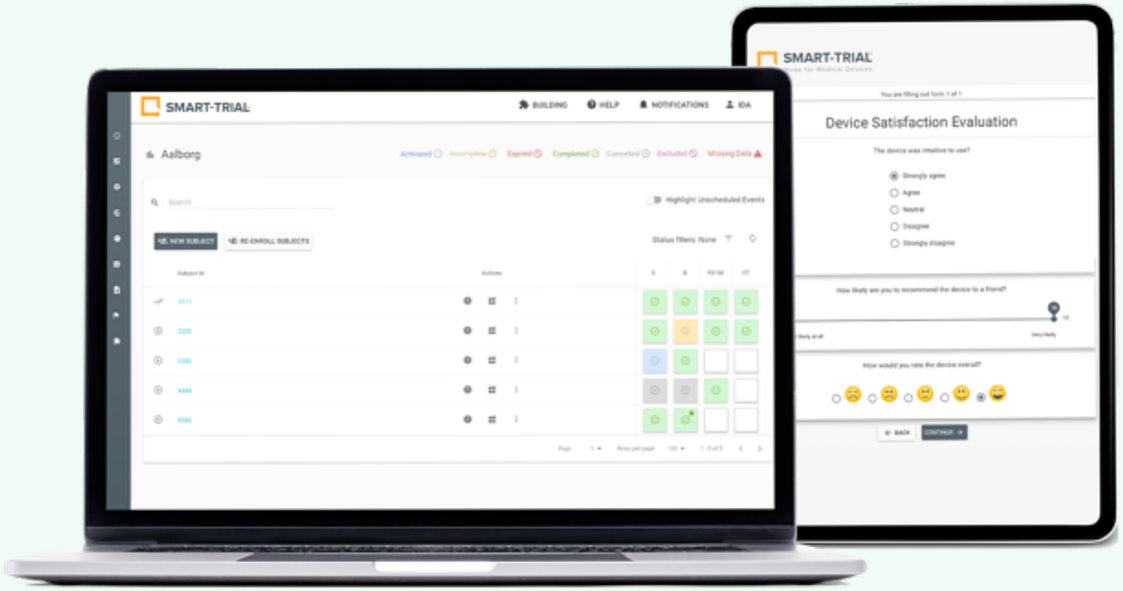


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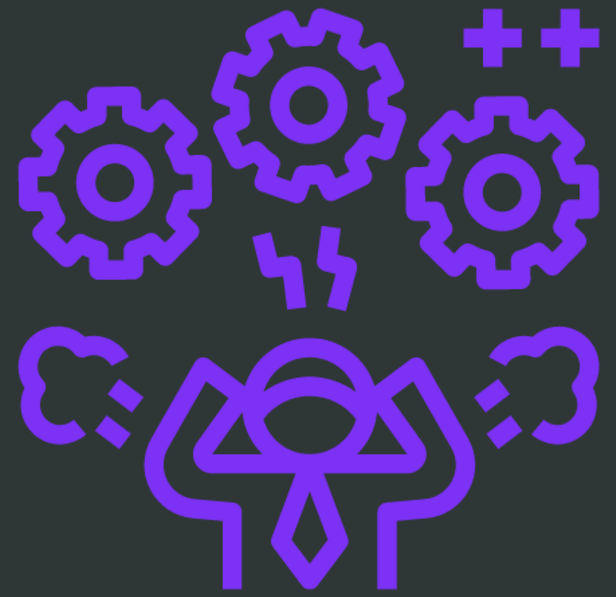

# Why This Topic?

Risk of products not getting approval (risk of product disapproval)

Too many manufacturers are forced to extend or repeat clinical studies.

Resulting in frustration, prolonged time-to-market, and missed revenue targets.

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# Strategy Development for Multiple Geographies

## Strategies and tactics

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# Strategy Development for Multiple Geographies

## Priority

Define your regulatory, marketing, and reimbursement goals.

## Regulatory Approval

The first step, not the ultimate/only goal.

## Multi-Team Effort

Clinical and regulatory program development is a multi-step and multi-team effort.

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# Program Development for Multiple Geographies

- Understand the regulatory and reimbursment requirements of each geography
- What product life-cycle stage is the devie in, by geography?
- What do end users want to know to adopt the device?
- Are my marketing claims the same in all geographies?
- What are the project timelines and budgets?

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# Clinical Strategy for Multiple Geographies

Consider the optimum study design for each geography

- Pre-approval vs post-approval studies
- Regulatory considerations, e.g. US Federal Regulations, ISO14155, GDPR
- Endpoints for regulatory approval, marketing claims, and reimbursement coverage

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# Diving In

## Statistical Considerations

- Endpoint development; regulatory, marketing, reimbursment
- Data poolability across studies and geographies

## Protocol Development for Multiple Geographies

- Regulations and guidances
- Medical practice patterns
- Population similarities and differences

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# Combining Clinical Strategies in Multiple Geographies

From complex to efficient

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# Combining Clinical Strategies for Multiple Geographies

## Classification

Does your device(s) have similar classification

## Indication, Purpose, Benefit

Difference in indication, intended purpose and intended clinical benefit

## Equivalence

Can you claim equivalence vs substantial equivalence

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# Clinical Data

## Data in Region?

Is there any data in the region that can be used, how?

## What is Needed?

What clinical data is needed in each region to meet the requirements for regulatory, marketing, and sales?

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# Pre- and Post-Market Studies (EU/US)

- Overlap between the US and the EU
- Determine how most cost effectively you can use data from one region in the other region

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# Keeping the Head Above Regulatory Differences

## Overcoming common pitfalls with legal issues

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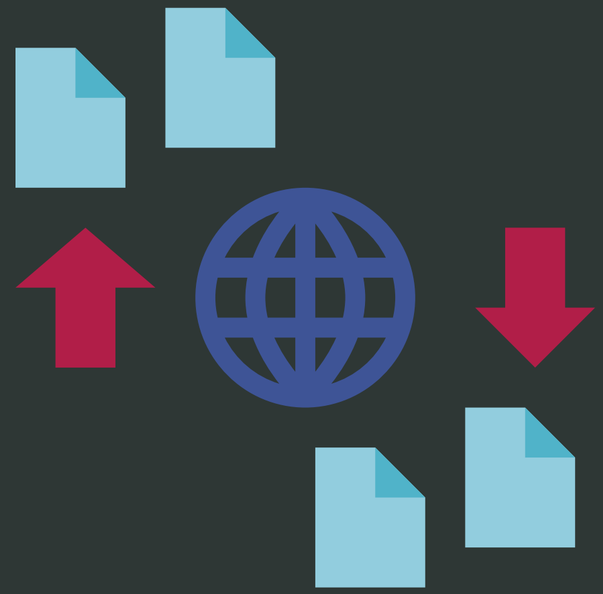
# Data Processing Consent

- Data processing consent (GDPR) must be collected from EU citizens (not integrated into ICF)
- Subject data collected on EU citizens cannot be transferred to the US without consent
- No US law that prohibits data transfer to the EU (CCPA might require data consent)

California Consumer Privacy Act



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# Good Clinical Practice

- EU MDR enforces "Good Clinical Practice" for Clinical Investigations
- Standard to follow in EU is ISO 14155:2020
- Local ethical requirements can differ within EU and outside of EU in Europe

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# Good Clinical Practice

- FDA enforces "Good Clinical Practice" for Clinical Investigations
- FDA defines "Good Clinical Practice" as 21 CFR 50, 54, 56, 812; Part 11
- ISO 14155:2020 can be used to comply with 21 CFR 812.28

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# Time for

# Q&A

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## It Takes Avania.

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