Real-world data collection in times of GDPR
HTAi 2021
A new challenge for medical-device manufacturers

Medical Device Regulation (MDR)

GDPR

RWD
Complaint and incident reporting data “cannot generally be considered sufficient to provide proof of safety.”

Do medical benefits outweigh the risks?

Time to plan

What has changed:

What is new:

What it means:
All this in the shadow of GDPR
All this in the shadow of GDPR

Increased clinical, device-specific data needs

Data collected should have minimal bias and be representative
All this in the shadow of GDPR

Increased data protection requirements:
• Data minimization
• Accuracy & Purpose

Data collected should minimize patient identification
All this in the shadow of GDPR

Data collected needs to be actionable
All this in the shadow of GDPR

Data collected needs to be relevant to practice
What about electronic medical records?
IMPRES(S) with CORZVA Scientific

**Consider**
- **INDICATION:**
  - Which populations and procedures are the target?
- **MEDICAL BENEFIT:**
  - How does it benefit? How to measure this?
- **PRODUCT:**
  - What is the product, its function, and where will it be used?

**Measure**
- **RESOURCES:**
  - How does the product impact care and costs of care?
- **EFFICACY:**
  - Patient & hospital outcomes
- **SAFETY:**
  - Any patient or user harm?

Do the costs & benefits justify the use of the health technology?
CONSIDER: Roundtable on stakeholder needs

- Does the health system benefit from this product?
- Does it fill any needs?
- Are the costs reasonable?
CONSIDER: Roundtable on stakeholder needs

**Regulatory**
- Does the health system benefit from this product?
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**GDPR**
- Is the patient's privacy respected?
- Do we have a legal justification?
- Can we improve anonymity?
CONSIDER: Roundtable on stakeholder needs

**Manufacturer**
- Can I show the value of my product?
- How can I use the data for other populations?
- Is there medical benefit?

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- Can I show the value of my product?
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**Clinician**
- Is this product efficacious?
- Can it improve patient safety?
- Does it add to or reduce my burden?
Example IMPRES program – Longitudinal data collection

**Desk research**
- Understand risk factors
- Understand outcomes
- Identify improvement targets

**Legal basis**
- Identify legal basis
- Reduce risk for identification by pseudonymization
- Limit collected parameters

**Collection design**
- Mask patient ID
- Control data access
- Control data flow
- Encrypt at all stages
- Optimize workflow

**Collection practice**
- React swiftly to issues
- Monitor for correct input
- Monitor for device functionality

**Analyse**
- Check for data consistency
- Deidentify data

**Report**
- Report aggregate data
- Avoid reporting bias
- Limit report access

**Communicate**
- Abstracts / Posters
- Presentations
- Manuscripts
Two real world examples

Respiratory monitoring
- Data collection based on published checklist for efficacy and safety events
- Anonymized data collection

Depth of Anaesthesia
- Data collection designed following guidelines and match pilot site workflows
- Pseudonymized patient tracking system

>10,000
- patients

12
- hospitals

10
- countries

3
- continents
Two real world examples: Pros and cons

Respiratory monitoring
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+ Roll out
+ Cost
+ Real world
- Bias
- Confounders

>10,000 12 10 3
patients hospitals countries continents
Thank You

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