

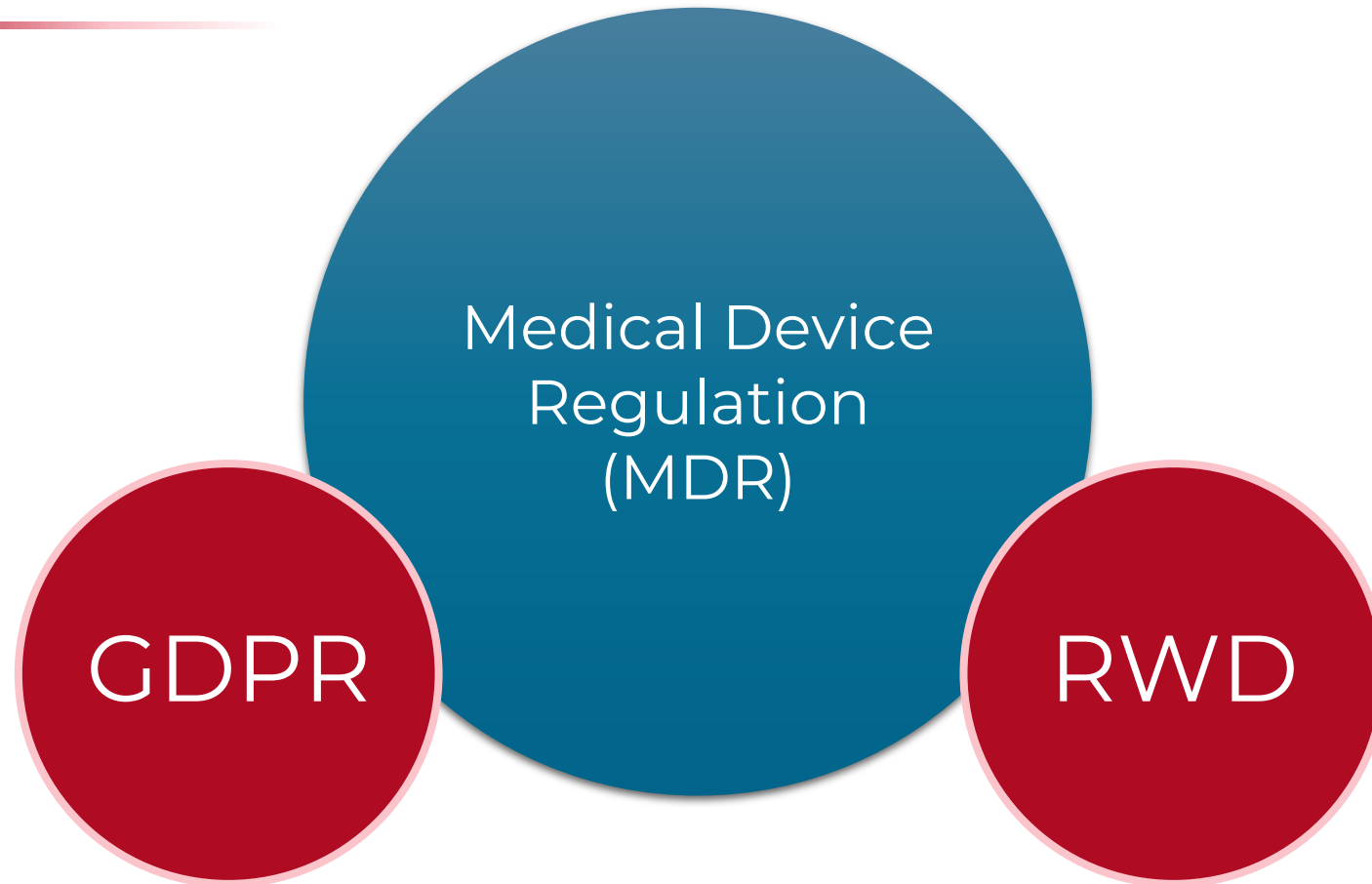
# CORVA Scientific



Real-world data collection in times of GDPR  
HTAi 2021

# A new challenge for medical-device manufacturers

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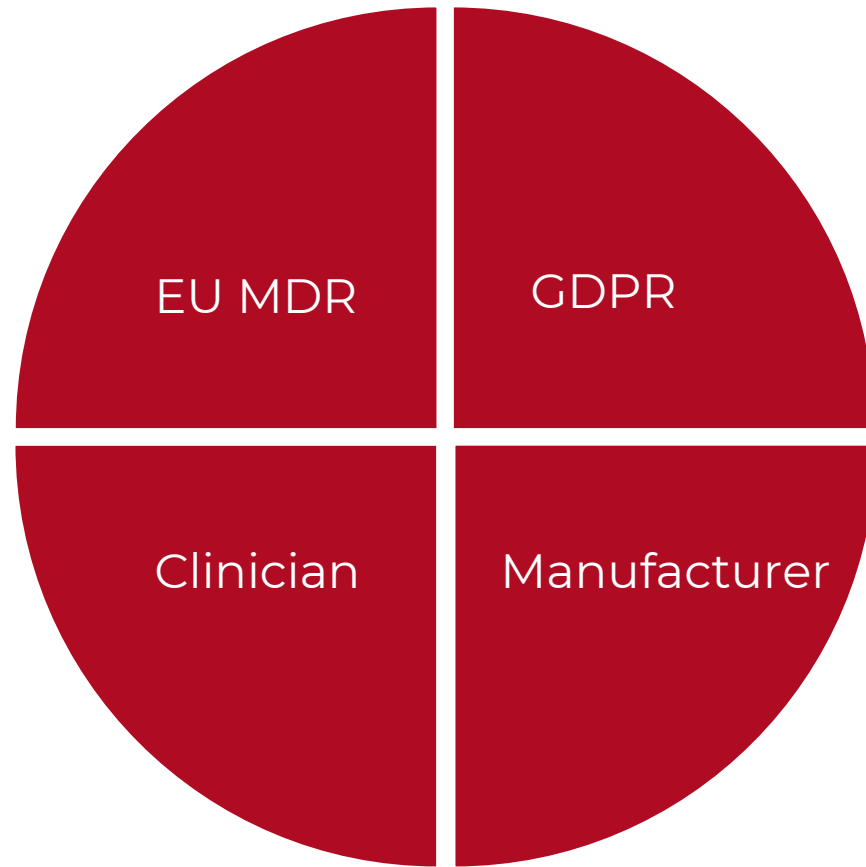


# MDR & its implications for manufacturers



# All this in the shadow of GDPR

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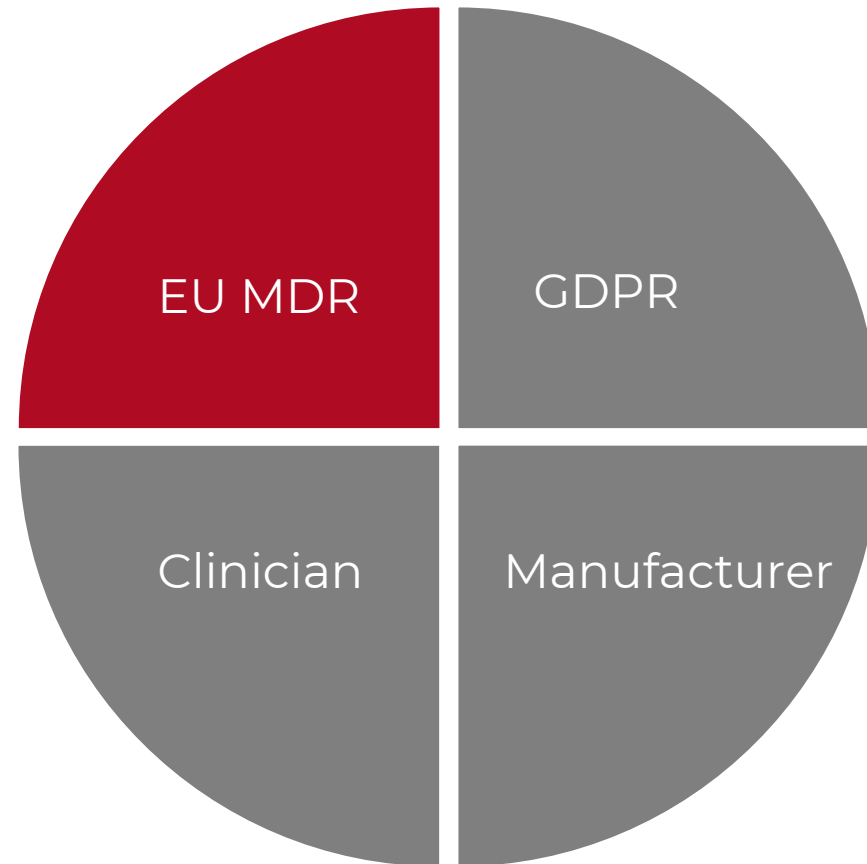


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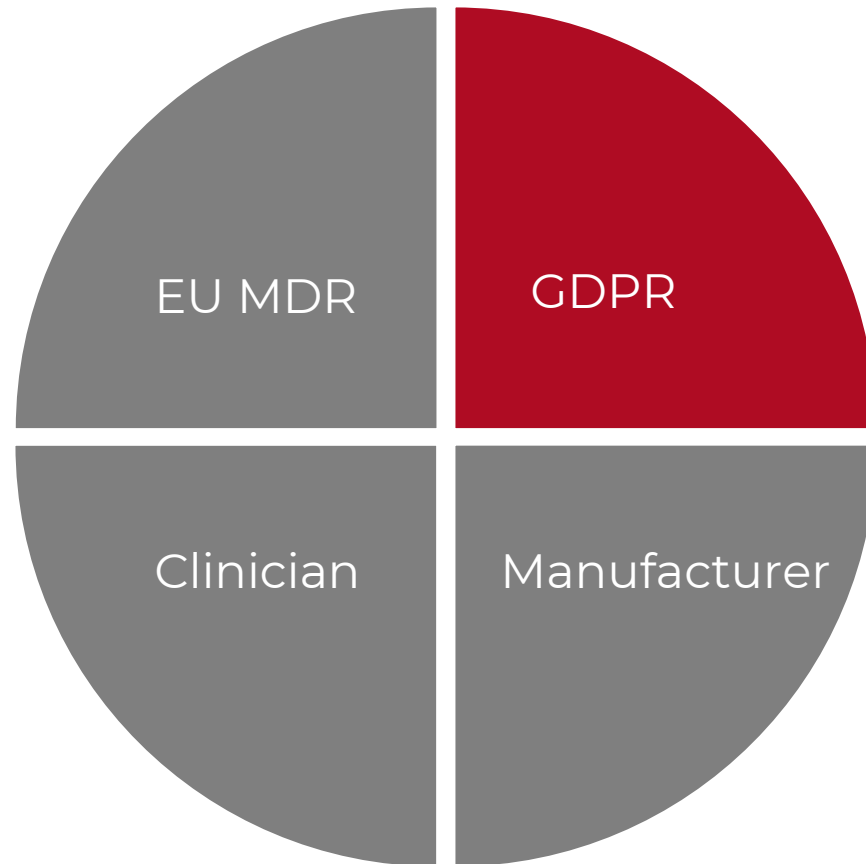
Increased clinical,  
device-specific data  
needs

Data collected should  
have minimal bias and  
be representative



# All this in the shadow of GDPR

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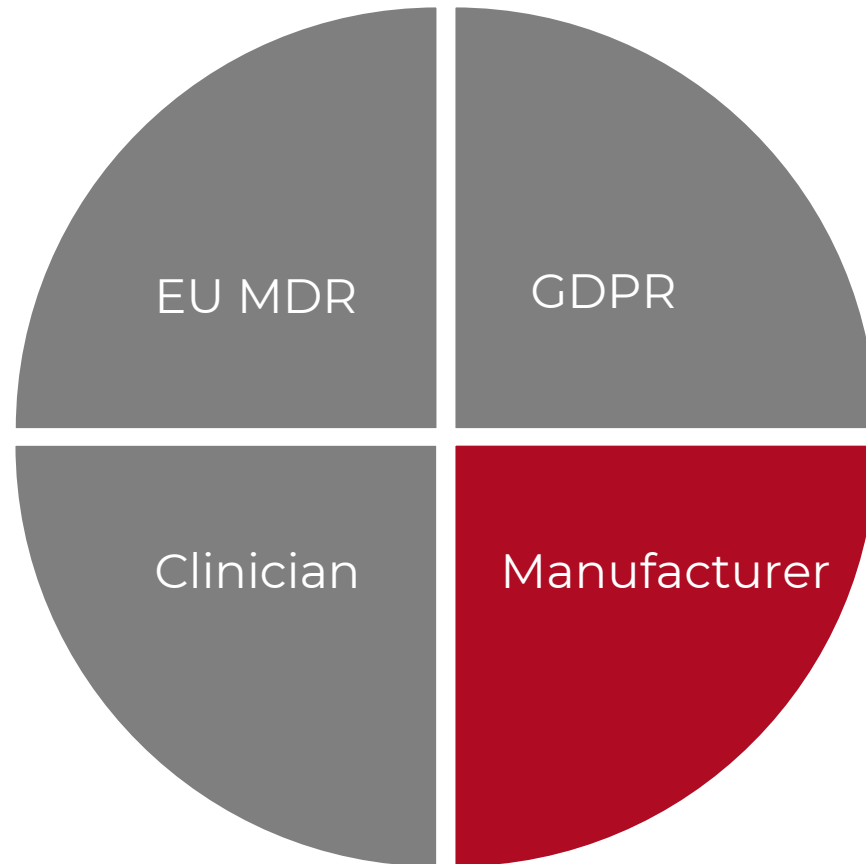
Increased data protection requirements:

- Data minimization
- Accuracy & Purpose

Data collected should minimize patient identification

# All this in the shadow of GDPR

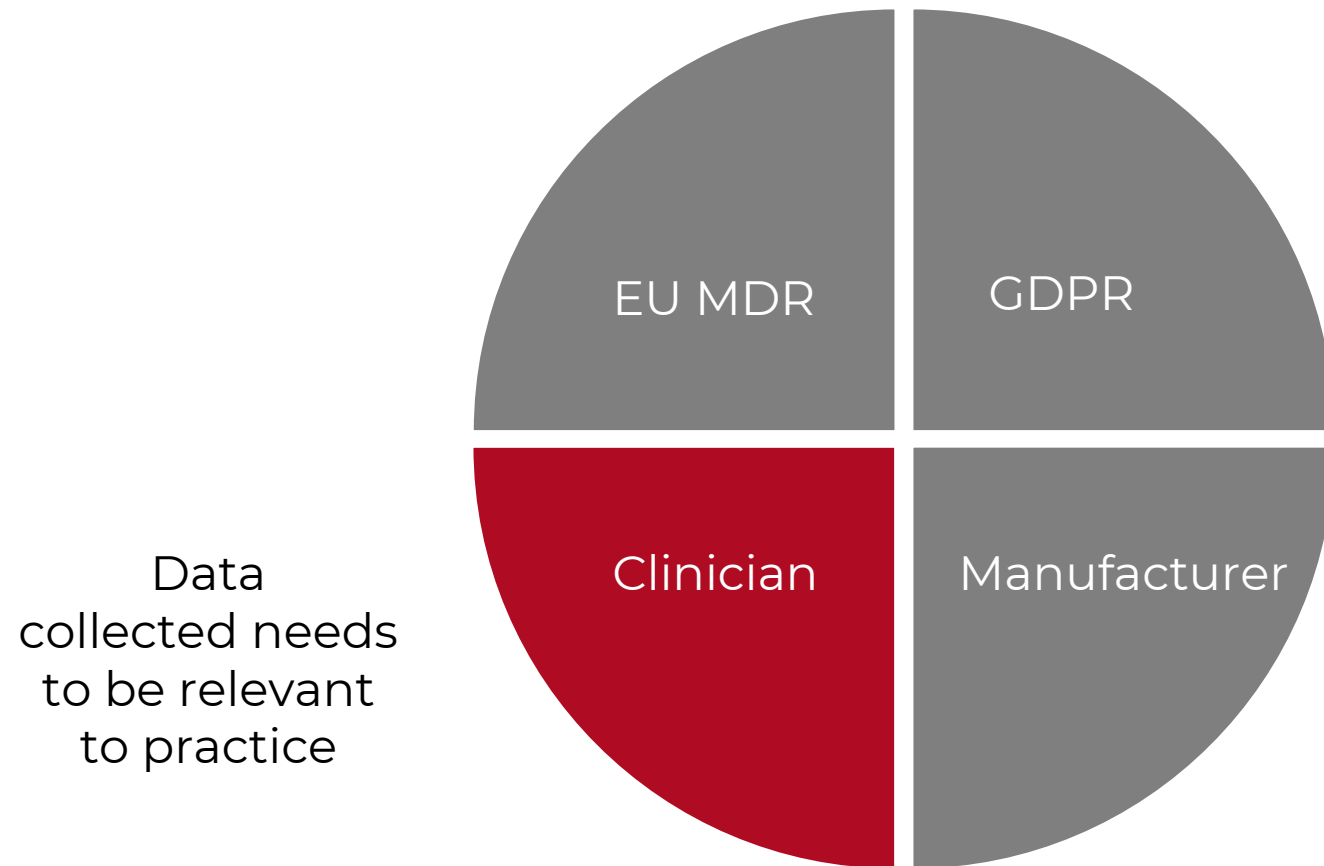
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Data collected  
needs to be  
actionable

# All this in the shadow of GDPR

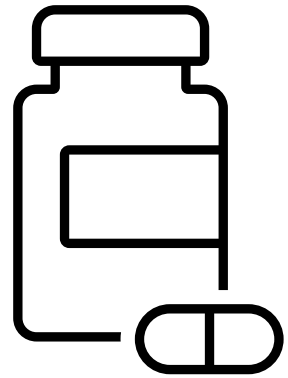
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# What about electronic medical records?

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# IMPRES(S) with CORVA 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

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## Regulatory



- Does the health system benefit from this product?
- Does it fill any needs?
- Are the costs reasonable?



# CONSIDER: Roundtable on stakeholder needs

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- Is the patient's privacy respected?
- Do we have a legal justification?
- Can we improve anonymity?

## GDPR



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## GDPR



## Manufacturer



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

# CONSIDER: Roundtable on stakeholder needs

## Regulatory



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## Manufacturer



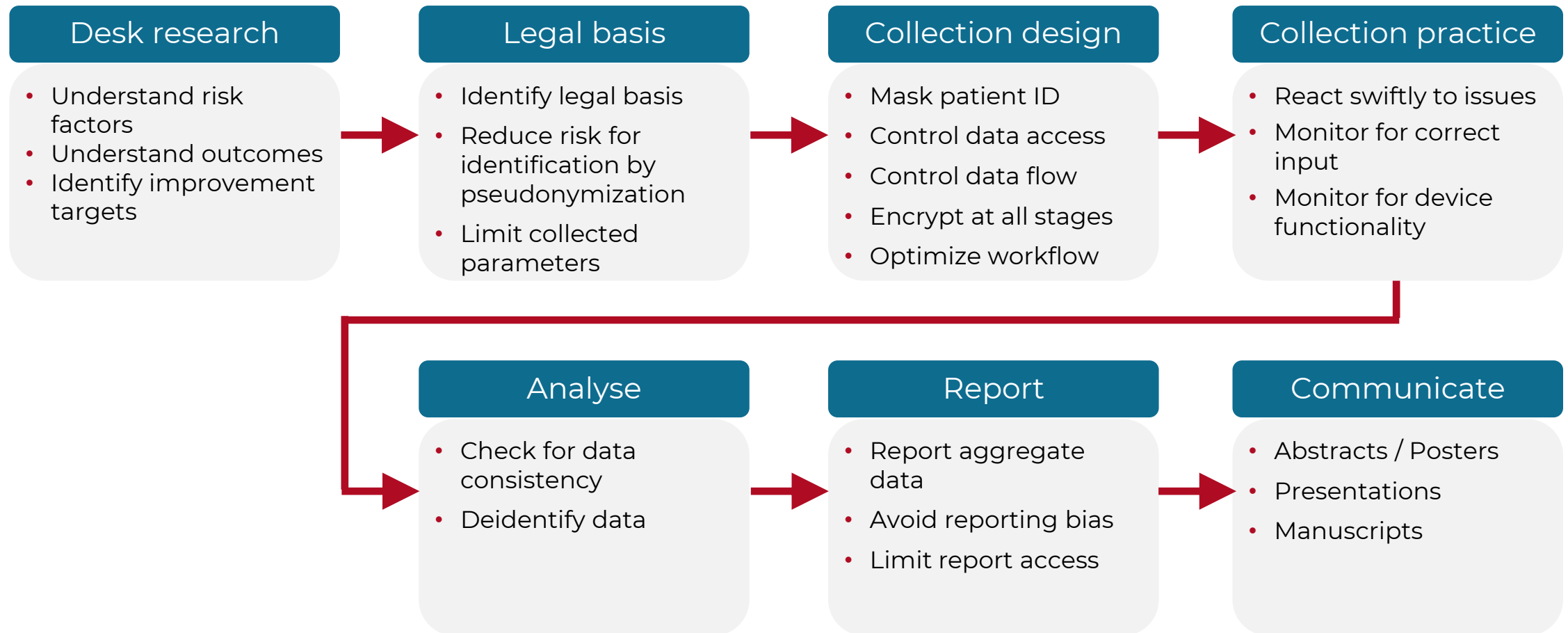
- Can I show the value of my product
- How can I use the data for other populations?
- Is there medical benefit?

- Is this product efficacious?
- Can it improve patient safety?
- Does it add to or reduce my burden?

## Clinician



# Example IMPRES program – Longitudinal data collection



# Two real world examples

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## Respiratory monitoring

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- Data collection based of published checklist for efficacy and safety events
- Anonymized data collection

## Depth of Anaesthesia

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- 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

- Data collection based of published checklist for efficacy and safety events
- Anonymized data collection

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

## Depth of Anaesthesia

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

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# CORVA Scientific



Thank You

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