Emerging medical device technologies and use of real-world data

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Definition of Real World Evidence (RWE)

Data regarding the usage, or the potential benefits or risks, of a therapeutic good derived from sources other than traditional clinical trials

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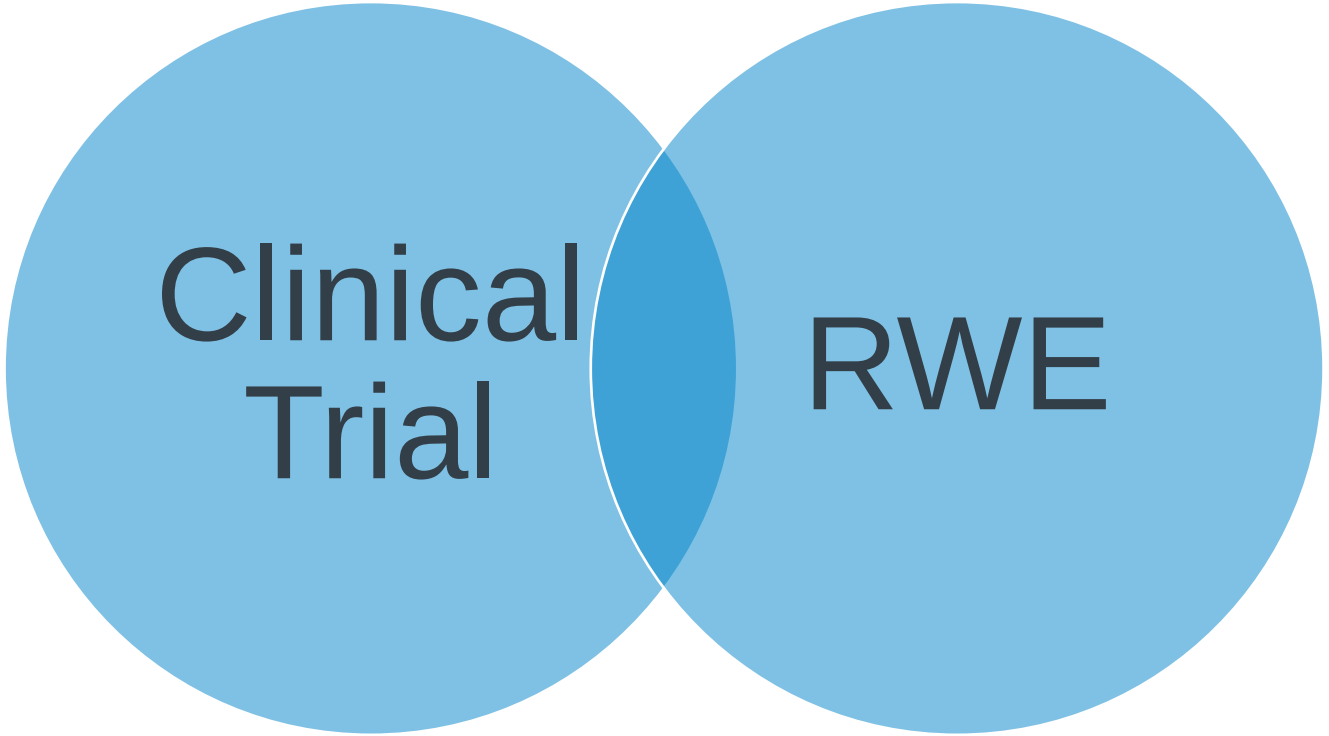
Real World Data (RWD)

Data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources:

- Primary or Secondary
  - Electronic Health Records (EHRs)
  - claims and billing activities
  - product and disease registries
  - patient-generated data including in home-use settings
  - data gathered from other sources that can inform on health status, such as mobile devices


Clinical Trial
RWE

Medical device life cycle

Possible applications of RWE

- Pre-market evaluation – *limited so far*
- More relevant for change in intended purpose or indications
- Post-market clinical follow-up

Data considerations

- Purpose of collection (primary vs secondary)
- Study design
- Prospective vs retrospective
- Statistical analysis

RWE

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Abracadabra

Registries as a source of RWE

Registry data use in regulatory decision making on high risk (class III) devices

- Note variation across registries with respect to data analysis and populations covered.
  - E.g. reoperations which are considered a revision in one registry are not considered a revision in another registry.
- Registry data guidance is provided in the following chapters of TGA's Clinical Evidence Guidelines for Medical Devices
  - Personalised medical devices
  - Total and partial joint prostheses
  - Cardiovascular devices to promote patency or functional flow
  - Implantable pulse generator systems
  - Heart valve prostheses
  - Surgical meshes

Evaluation

Real-world data (RWD)

- Study design
- Data quality
- Prespecified analysis plan
- Bias and confounding

Real-world evidence (RWE)

Essential Principle 14:
Every medical device requires clinical evidence, appropriate for the use and classification of the device

Emerging technologies

Main experience and focus so far:

- Software as a medical device (SaMD)
- Personalised medical devices (PMDs)

Common theme:

- Connected devices

Connected devices

What are connected devices?

Newer technologies incorporate software that may facilitate data collection

Data is transmitted to the manufacturer or clinic (web interface)

Data opportunities

Post-market clinical follow-up (PMCF) studies –utilise data to power outcomes

Considerations

RWD

- May be from apps, sensors, IVDs, EMRs, GP software, telehealth, other sources such as consumer devices
- Existing obligations under Regulations and Essential Principles
- Specific RWD issues
  - Governance framework
  - Collection and how it is used, feeds into analytics
  - Storage – on devices, cloud, which jurisdictions, copies
  - Third party access – APIs, on selling,
  - Security
  - End of life – disposal, retirement, porting
  - Other obligations, privacy, consent

RWE

- How to augment clinical trials
- When to use synthetic data vs RWE, hybrid approaches
- Real world evidence is not a substitute for testing functionality
- Technical and analytical validation of software is still required
- What circumstances best fit RWE – what kinds and sources of data, structured/unstructured, what gaps or mismatches exist in data, what is the fit of the data to the scope of the software?
- For AI, the match between the training and testing data populations, and the population deployed to for the real world evidence, and how does that relate to the ultimate target population

Who can use it?

Possible practical applications

Manufacturer use

- Novel clinical trial designs
- Use of data from different sources
- How do we use this data/what does it tell us

TGA use

- Australian and International registries
- What is in/out
- Use in various regulatory activities

Contact us at TGA

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Website references

TGA website	www.tga.gov.au
RWE Hub	www.tga.gov.au/real-world-evidence-rwe-and-patient-reported-outcomes-pros
Medical device RWE and PRO	www.tga.gov.au/real-world-evidence-and-patient-reported-outcomes-medical-devices
Clinical evidence guidelines for medical devices	www.tga.gov.au/resources/resource/guidance/clinical-evidence-guidelines-medical-devices

Therapeutic Goods Administration (TGA)

Exhibition booth **No.1**

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