Industry Sponsor Experiences with NMA and Opportunities to Enhance

Medical Device Industry Perspective

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Agenda

- Medical Device Trials
- Opportunities to Enhance the NMA
- NHMRC National Scientific Committees
- MTAA CIRA

Clinical Trial Activity in Australia

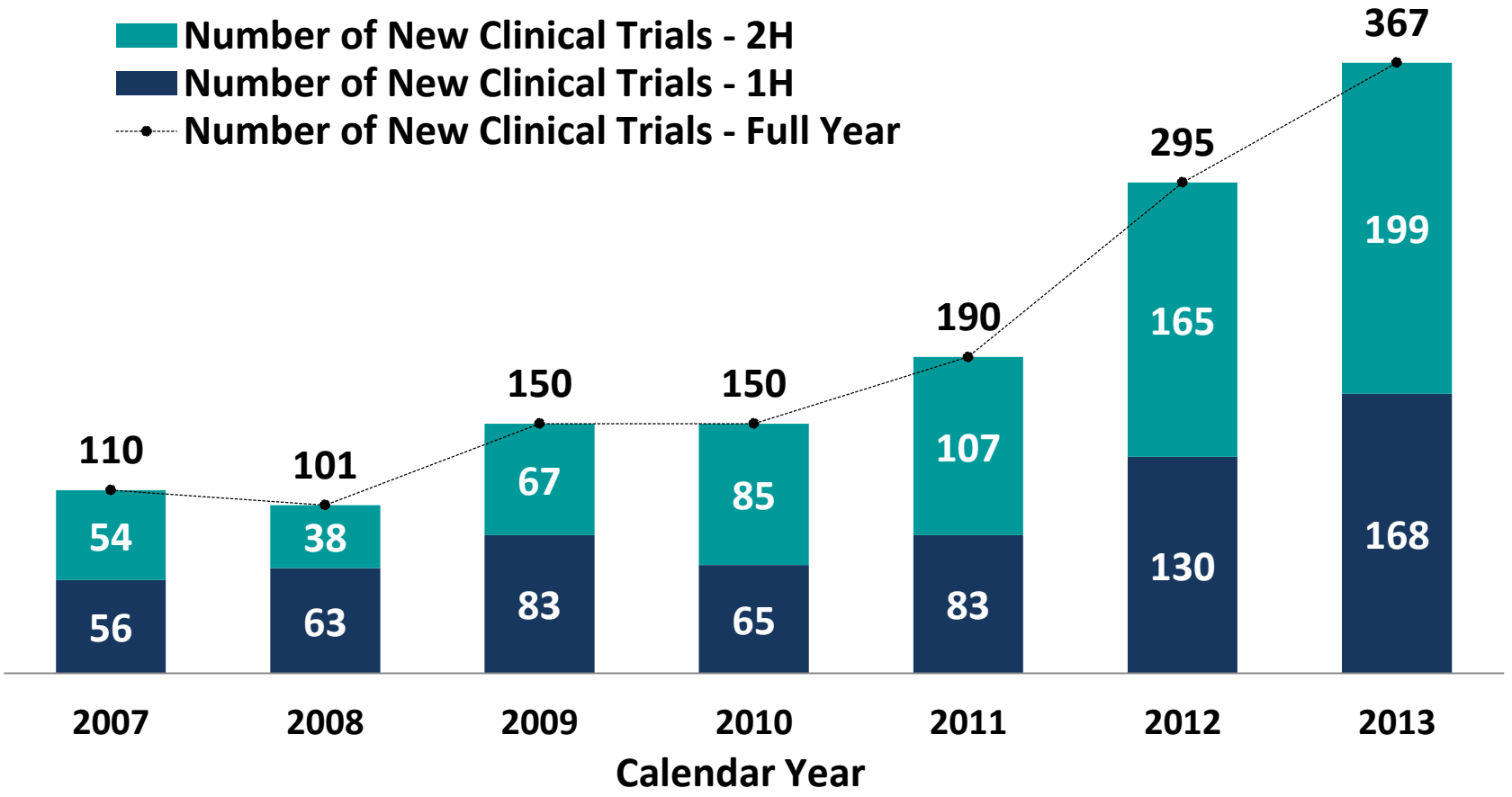
New clinical trials by Therapeutic Good (Jul-Dec2015)

Therapeutic Good Type	Percentage
Medicine only	52%
Medical devices only	**14%**
Medicine and medical device	**28%**
Biologicals only	2%
Medicine and biological	2%
Medicine, medical device and biological	1%
Total number of clinical trials over period	**469**

42%

Source: Therapeutic Goods Administration Half Yearly report July-December 2015

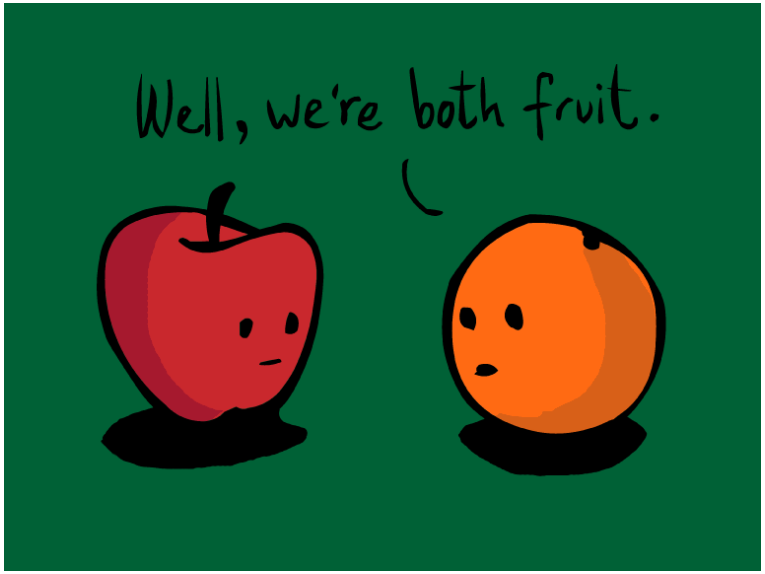
Number of New Clinical Trials - Medical Devices



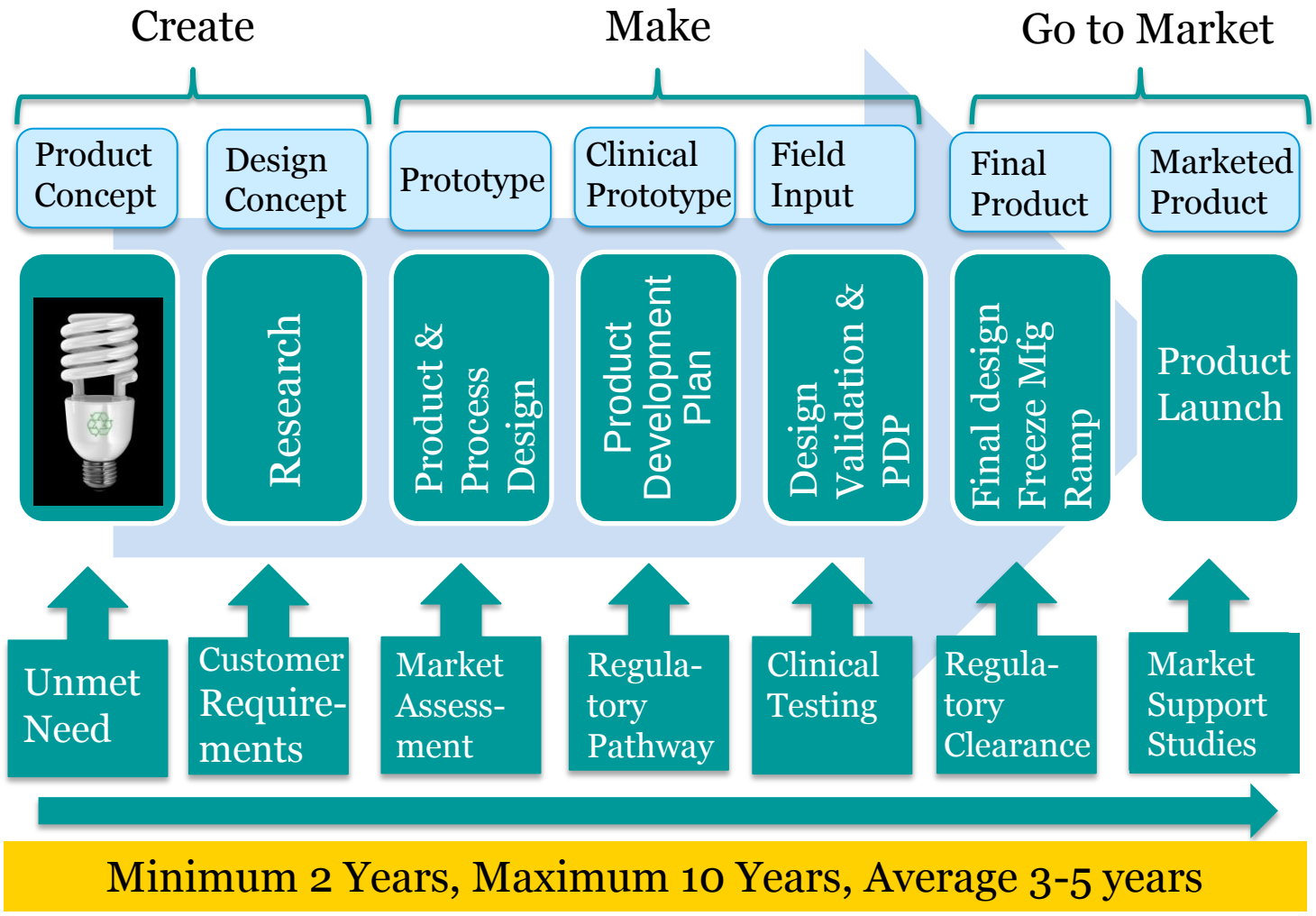
Source: Therapeutic Goods Administration, Half-Yearly Performance Reports, Clinical Trials (Medical Devices)

Medical Devices versus Drugs

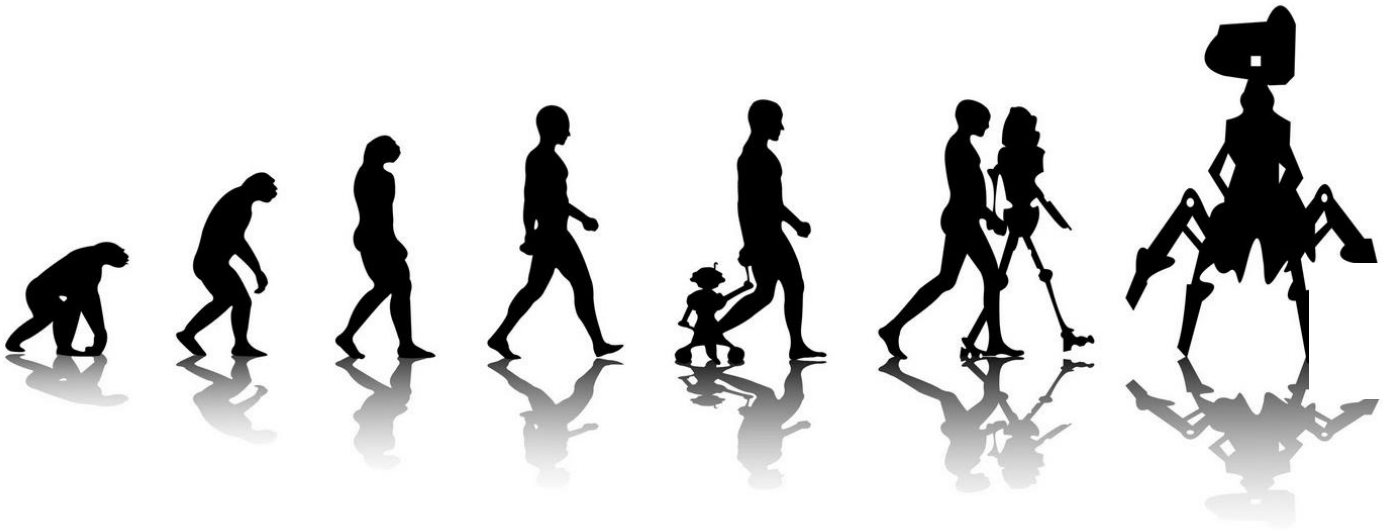
VS



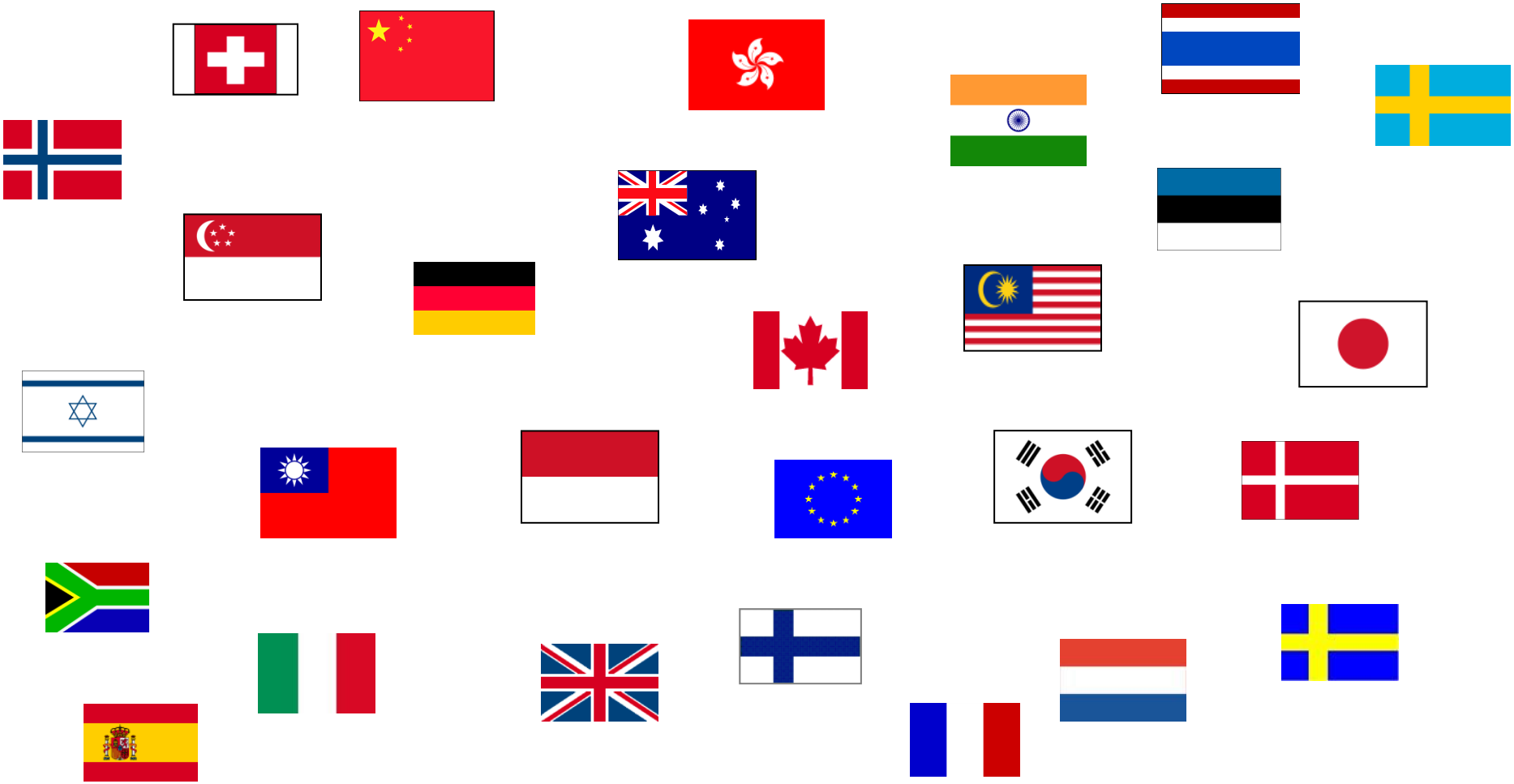
Medical Device Development Life Cycle



Evolution of Medical Devices



Global Competitiveness for Clinical Trials



Country Selection for Clinical Trials

Quality	• ICH Good Clinical Practice, medical expertise, translational expertise
Recruitment Capacity	• Reliably recruit patients committed, size of patient contribution
Speed	• Rapid start up, rapid patient recruitment
Cost (Value)	• Cost (per patient including labs), efficiency (pts/site; pts/CRA)

AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH

ANALYSIS OF RECENTLY CONDUCTED CLINICAL TRIALS

FINAL REPORT
20 AUGUST 2015

Analysis of Recently Conducted Clinical Trials

Objectives

1) The key barriers to a sponsor's decision to not place a trial in Australia, and/or a trial conducted in Australia that fails to deliver

2) The key enablers leading to successful completion of a trial

Project conducted February 2015 - June 2015.

Analysis of Recently Conducted Clinical Trials

Key Enablers:

- CTN scheme.
- National Mutual Acceptance Scheme.
- Short ethics review timeframes for private sites.
- Experienced researchers and site study coordinators.
- Standardised costing or corporate 'fair market stipulations' to assist with budget negotiations
- Robust feasibility assessments and honest patient recruitment estimates
- Established referral networks and national patient databases.

Analysis of Recently Conducted Clinical Trials

Key Barriers:

- No national single ethics approval process
- Lack of consistency in Human Research Ethics Committee (HREC) requirements
- Lack of clarity, consistency, transparency and timeliness of governance approvals
- Inability for sponsor organisation to communicate directly with HREC or RGO.
- Inaccurate feasibility assessments and unclear accountability for delivering recruitment targets within institutions
- Lack of awareness and support for clinical research.

Analysis of Recently Conducted Clinical Trials

Key Barriers:

- Lack of clarity, consistency, transparency and timeliness of governance approvals
- Inability for sponsor organisation to communicate directly with HREC or RGO
- Lack of awareness and support for clinical research.

NHMRC

National Scientific Committees

The NHMRC National Scientific Committees (NSC)

The NHMRC NSC hosted by Bellberry Limited

Complex genetic research & medical device trials.

Provides advice to HRECs, sponsors and researchers on the scientific merit and integrity of a research protocol.

Investigator / Sponsor
Used to contribute to the development of the research proposal.

HREC
- Inform the scientific review conducted by the HREC
- Used by an HREC to replace that scientific review.

Pilot: 30 reviews, no cost, 3 week turnaround

MTAA

Clinical Investigation Research Agreement (CIRA)

Abbott