



Improving the Environment for Clinical Trials in Australia

Manager – Process, Training & Quality

International Clinical Research Operations & Oncology Global Monitoring Organisation

Novartis Pharmaceuticals Australia



Improving the Environment for Clinical Trials in Australia

- Sponsor's View:
 - Why do we need to continually improve?
 - What value could Australia lose?
 - What are the current initiatives to improve?
 - What else could we do?

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Changing global environment for drug development

- Attrition of new drug candidates continues to increase
- More data needed to get drugs approved
- Rapid escalation of the costs of R&D
- Companies face significant revenue cliffs on patent loss
- Increasingly difficult global environment for reimbursement

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Why do we need to continually improve?

- Trial allocation driven by productivity metrics
- Drive for productivity gains in clinical development
- Rising contribution of new markets/locations to global data pack
- Decreasing contribution of traditional markets/locations

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What value could Australia lose?

- Significant trial activity and investment
 - \$540 Million into health system per annum (best estimate)
 - ABS 2006-07 and MA Economic Survey*
 - More than 1,097 trials/projects
 - More than \$260 Million into health system per annum (only n=23)
 - PIC RDTF Benchmark Data 2008 Activity**

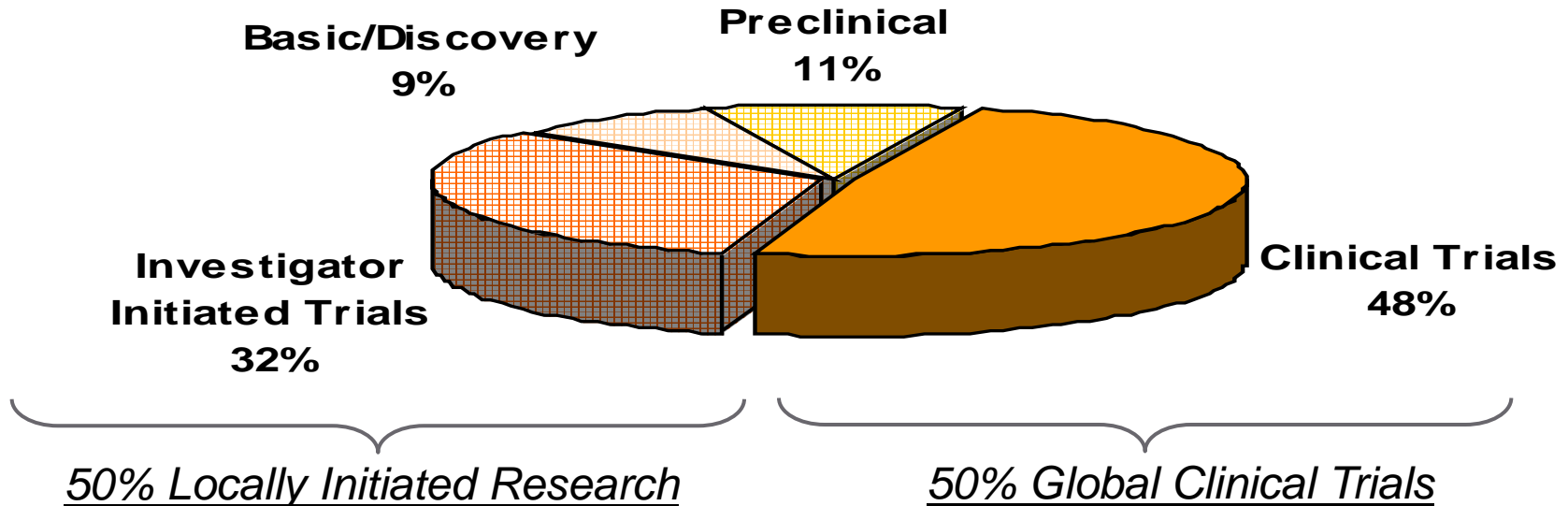
* ABS: \$587 million invested in 2006-07; MA Economic survey, 89% invested in clinical trials

** n = 23 global companies 2008 PIC RDTF Benchmarking Data – global trials/projects
5 | AusBiotech 2010 | Mitch Kirkman | 21 October 2010 | Ethics and Research Governance Forum

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What value could Australia lose? Local and Global Research

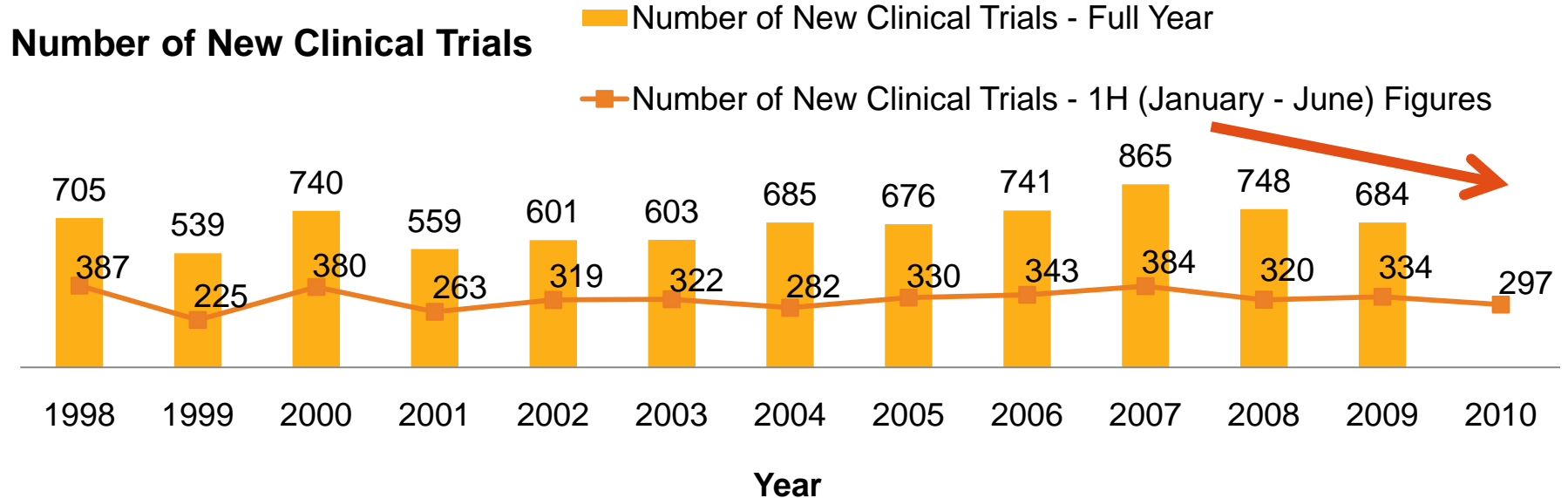
Global Companies: Type of R&D in Australia During 2008



* n = 23 global companies 2008 PIC RDTF Benchmarking Data – global trials/projects

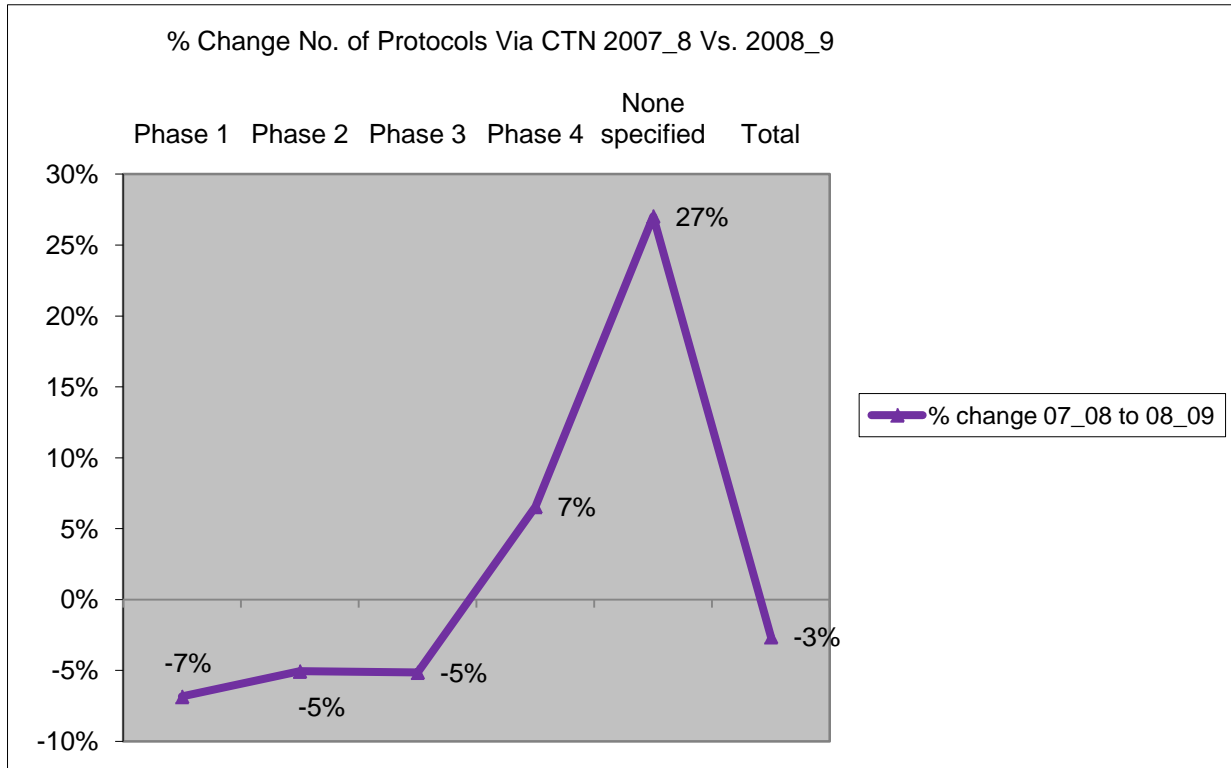
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Why do we need to continually improve?



Source: Therapeutic Goods Administration, CTN Data
[number of single site notifications and multiple centre protocols]

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Australia's Scorecard: **X** = under challenge

X Timeliness

- Rapid start up and rapid patient recruitment

X Recruitment Capacity

- Reliably recruit patients required for trials, size of patient contribution

X Value

- cost (per patient including all labs), efficiency (pts/site; pts/CRA)

✓ Quality

- ICH Good Clinical Practice, medical expertise, translational expertise

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- **Opportunities – not all doom and gloom !**
 - Early Phase (esp Phase I/II)
 - Translational medicine/biomarkers/tissue banks
 - E-Health (short term and long term)
 - Coordinated action for Phase II/III
 - to regain speed and reproducibility of start-up,
 - maximise recruitment with the population we have
 - improve cost competitiveness with like countries

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What are the current initiatives to improve?

- PIC Research & Development Taskforce (RDTF)
 - Four Pillar Model - Quality, Timeliness, Capacity (Recruitment), Value
 - National, streamlined approaches (esp. with jurisdictions)
 - Increase dialogue with key stakeholders (eg. annual national forum)
 - Gather data on value of clinical trials to Australia
 - Lobby for Government to lead coordinated & urgent action

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What are the current initiatives to improve?

- Pharmaceutical Industry Strategy Group (PISG)
 - Clinical trial recommendations:
 2. Accelerate implementation of national streamlined ethical approval process for multicentre clinical trials
 3. Accelerate implementation of e-health initiatives:
 - ensure electronic medical records in hospitals meet industry needs and
 - allow remote access for industry monitors
 4. Establish coordinated national patient referral networks, especially in therapeutic areas of high trial activity

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What are the current initiatives to improve?

- Pharmaceutical Industry Working Group
 - Clinical Trials Action Group
 - Ministers Carr and Roxon announced following September 2009 PIWG meeting
 - Terms of reference related to increasing clinical trials in Australia
 - Membership
 - » Parl Sec Richard Marles, Parl Sec Mark Butler (both now changed responsibility)
 - » Prof Jim Bishop, Chief Medical Officer Australia
 - » Dr Tim Dyke (& Prof Warwick Wilkinson), NHMRC
 - » Mitch Kirkman, PISG Industry Representative with expertise in clinical trials
 - Report submitted 18 June 2010 – await Government response

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What are the current initiatives to improve?

- Pharmaceutical Industry Working Group

- Clinical Trials Action Group

Terms of Reference:

- Developing a clinical trials roadmap
- Developing key performance measures for clinical trials
- Ensuring rapid uptake of streamlined ethics, scientific and governance processes
- Strategies to improve patient recruitment
- Developing an Information technology strategic plan for clinical trials (e- health)

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What else could we do?

- Coordinated action for Phase II/III multicentre trials
 - speed and reproducibility of start-up: national ethical approval
 - e-Health: ensure access for monitors to EMR (esp. remote)
 - maximise recruitment with the population we have
 - can we find an answer to effectively and efficiently access:
 - primary care patients
 - regional sites
 - improve cost competitiveness with like countries