

GSK R&D

Greenford (UK)



Harlow (UK)



Stevenage (UK)



RTP (USA)



Upper Providence
(USA)



Upper Merion
(USA)

Verona (ITA)



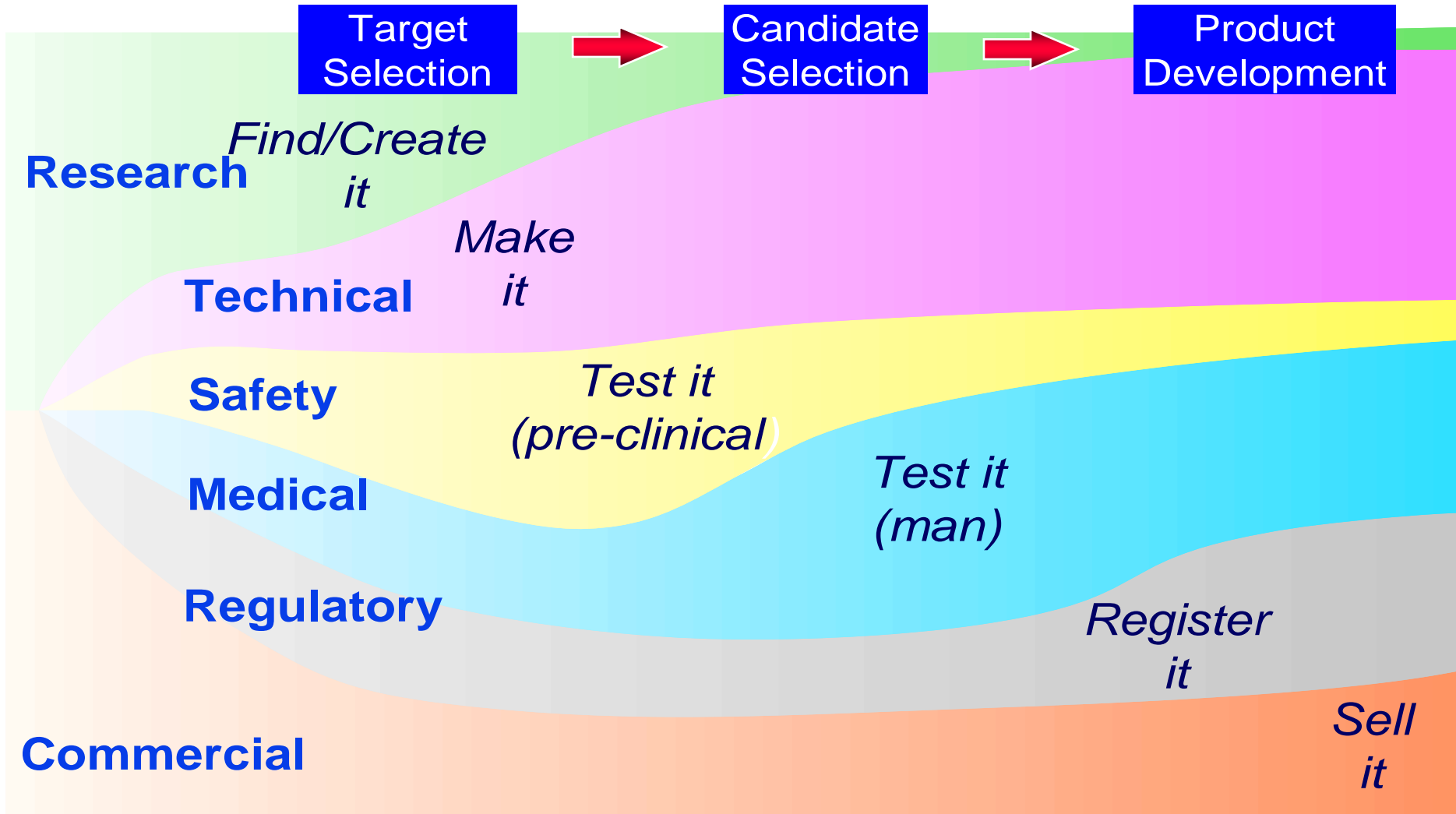
Tokyo (JPN)

Dr Ashley Bates
Discovery Research
GlaxoSmithKline Australia

GlaxoSmithKline at a Glance

- **Sales of almost \$30B**
 - In Pharmaceuticals, Vaccines, Consumer Healthcare
- **Over 100,000 employees.**
 - R&D: 15,000 employees, 20 sites, 8 countries, US\$3.5B annual investment
- **5000 Clinical, Regulatory staff in over 50 Countries**
 - An integrated organisation focused on rapid, efficient commercialisation
- **Manufacturing: 35,000 employees, over 100 manufacturing sites in 40 countries**
 - Supplies over 1,100 brands to 140 markets
- **In 2000**
 - Treated over 75,000 patients in clinical trials,
 - filed over 700 Regulatory submissions (NCE + PLEs)

R&D Roadmap - an “aide memoire”



R&D Roadmap



Discovery

Proof of concept

Full Development

Approval

Launch

Research

Chemical diversity and biological assay
Genetics (DGE)
Disease target identified

Patents
Assessment of developability
Drug candidate selection

Continuing research into the disease

Development of synthesis, formulation and means of production

Transfer to primary and secondary manufacture
Packaging and distribution to markets

New formulations

Technical

Chemical and biotechnology research, analytical methods and preliminary formulation

Quality assurance

Product Safety

Development Plan

Short term toxicology

Longer term toxicology

Oncogenicity and teratogenicity tests

Phase IV post-marketing surveillance

Medical

Absorption, distribution, metabolism and elimination
Surrogate markers

Phase III efficacy, safety and quality of life studies in patients

Phase III B peri-marketing studies

New indications

Regulatory

Phase I volunteer studies

Phase II patient safety studies

Further registrations in new markets

Commercial

Market Research
Target Product Profile

Communications with customers - investigators and markets
Health Outcomes

Marketing Authorisation Applications

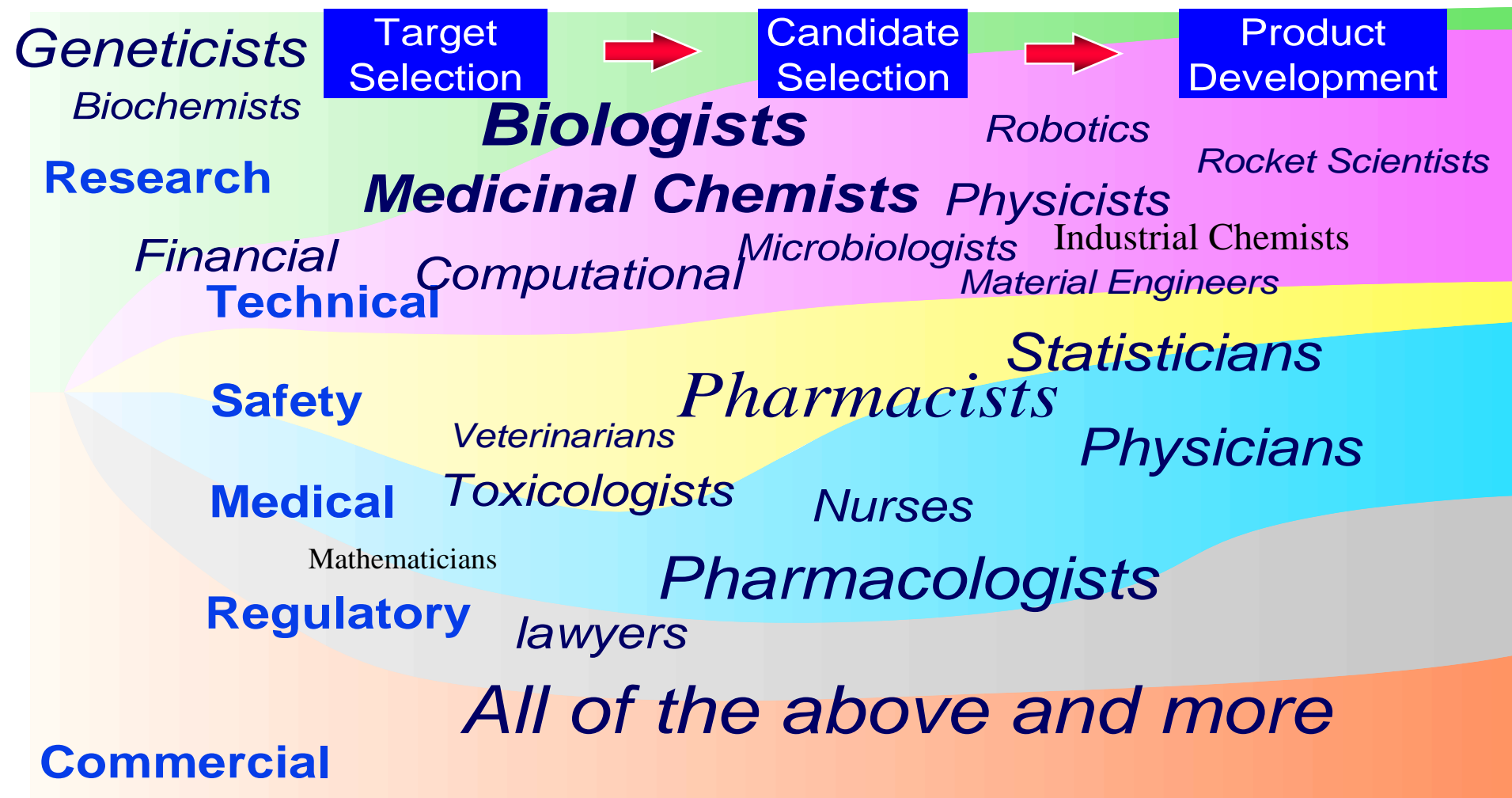
Product optimisation and transfer to market

TIME

10 to 14 Years

Some of the many activities undertaken during development of a new medicine

Pharmaceutical R&D



Ashley Bates

B.Sc. Chem: Heriot-Watt U, Edinburgh

Ph.D. Physical Chemistry: - Heriot-Watt U, Edinburgh

Formulation Scientist: Upjohn England (1 year)

Research Scientist: Upjohn MI USA (6 yrs)

R&D Mgt (Pharmacia & Upjohn Perth): Perth, WA - 3 yrs

Project Mgr Pharmaceutical Development (GlaxoWellcome): 1 year

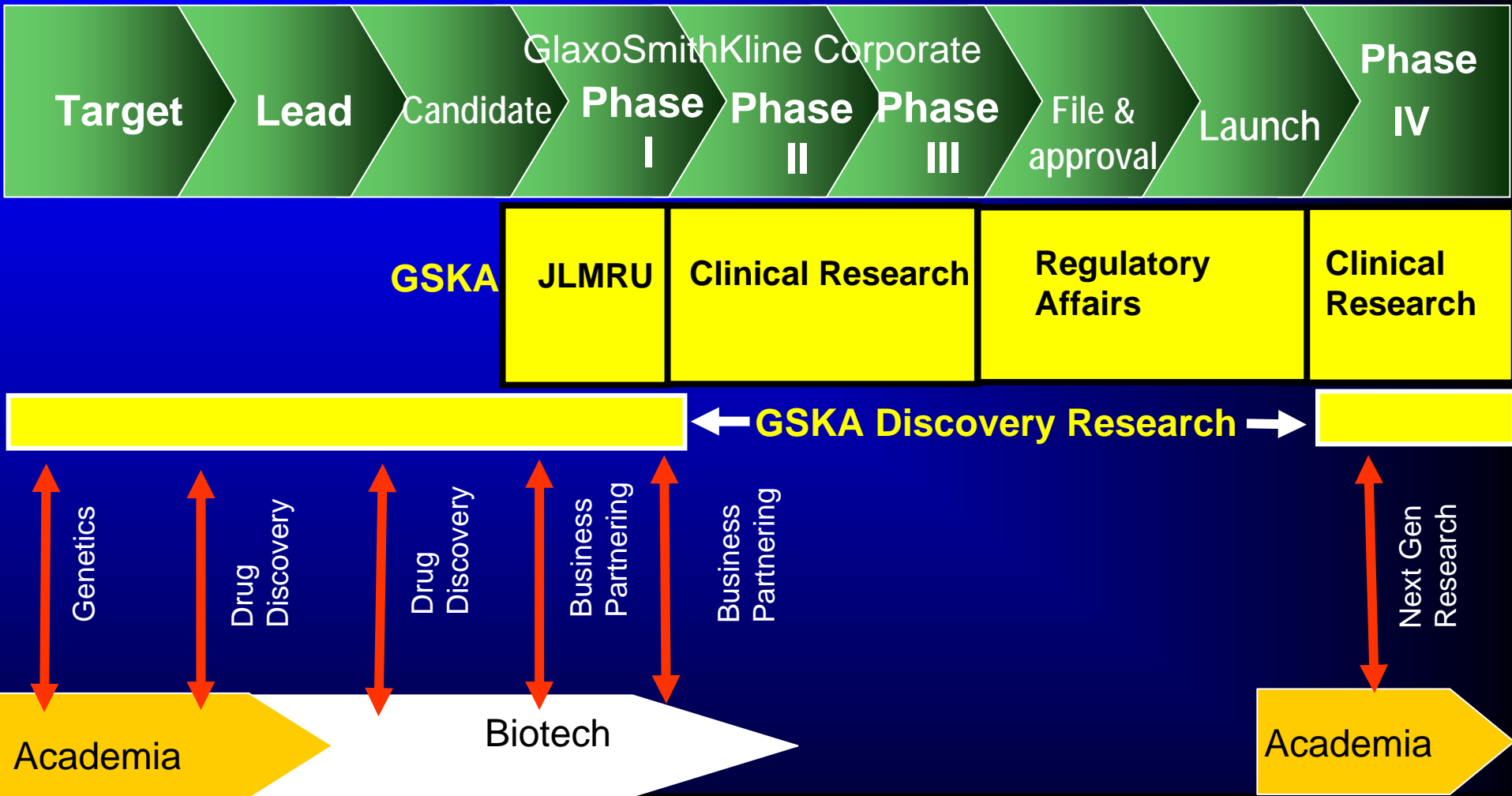
Head Pharmaceutical Development (GlaxoWellcome) 1year

Head Discovery Research (5 years).

The role of Discovery Research

- **Contribute to GSK R&D** by partnership with Australian researchers and innovation
- Leverage GSKA DR efforts to maximise direct and indirect **benefits to the local business**
- Support and encourage a sustainable Australian Research **environment**

GSK Australia's involvement in the R&D Process

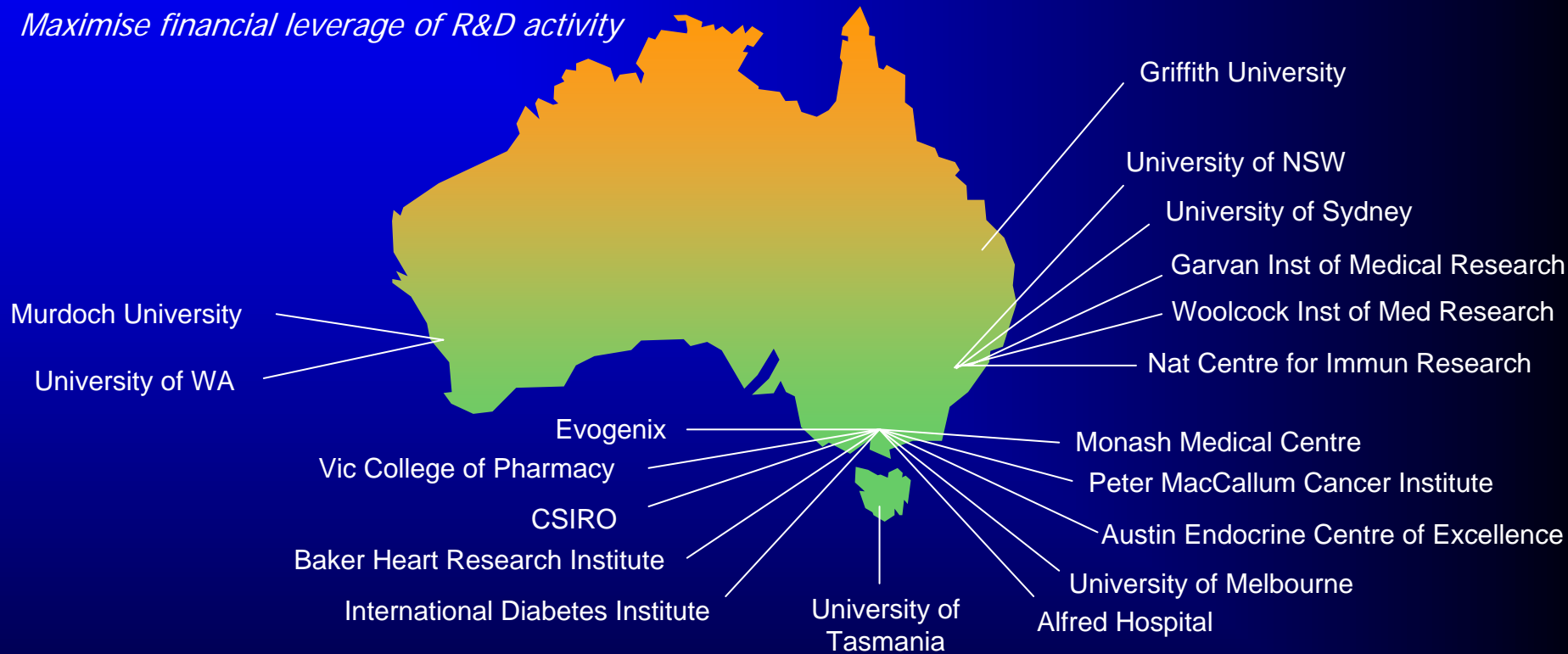


Discovery Research Australia

Activities:

- *Partner of choice activities*
- *Brokerage - Proactively seek new research opportunities*
- *Local management of existing projects*
- *Maximise financial leverage of R&D activity*

Over 35 projects in 2005



Target

Lead

Candidate

Phase
I

Phase
II

Phase
III

File &
approval

Launch

Phase
IV