Global Development in Asia

The Singapore Perspective

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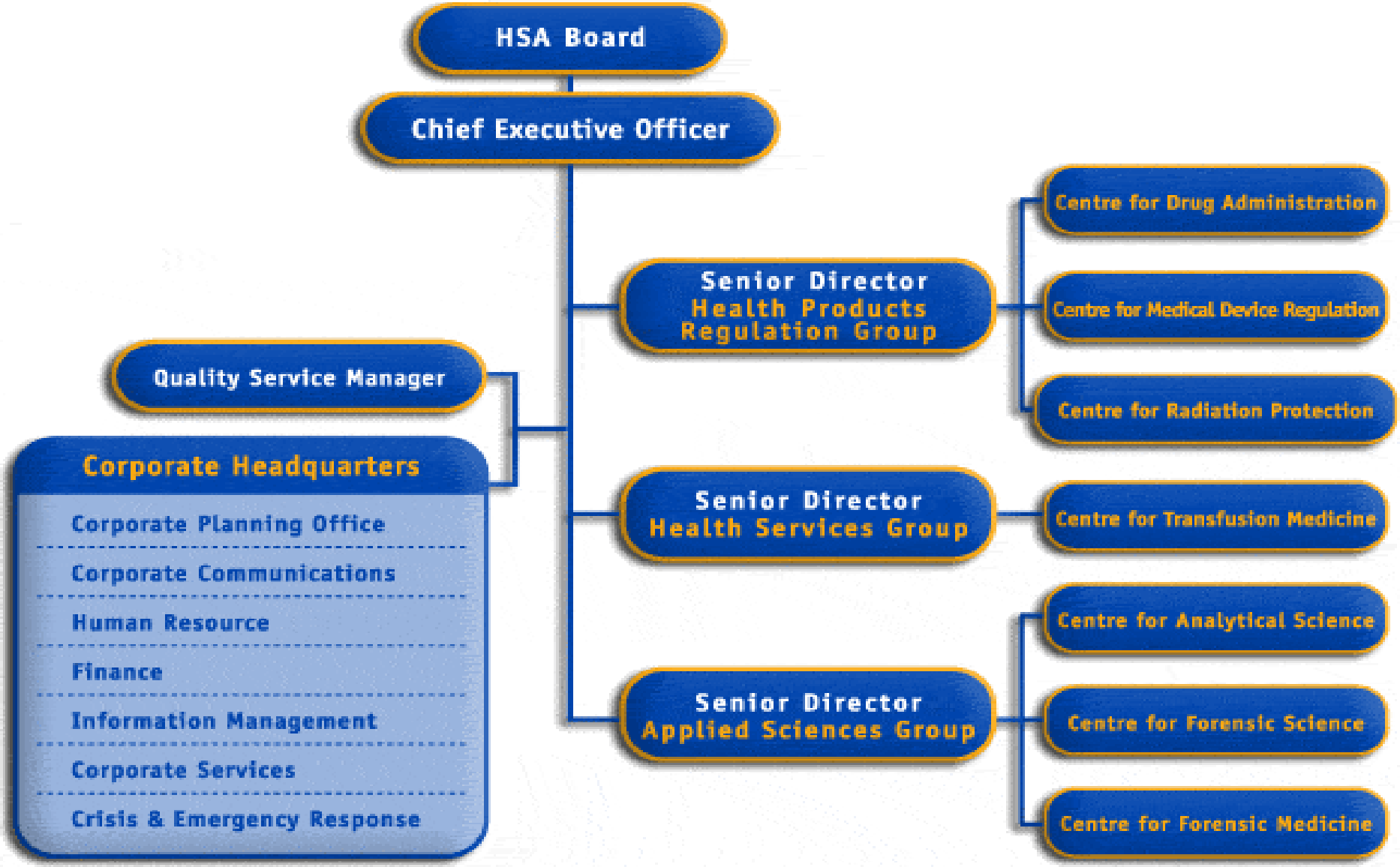
13 October 2006

Presentation Outline

- Overview of the Health Sciences Authority
- Singapore's Public Healthcare System
- Regulation of Clinical Drug Trials
- Clinical Trials Statistics and Trends
- Biomedical Sciences Initiatives
- Changing Regulatory Paradigms

HSA Organisation Structure



Mission and Vision

Vision

to be the **LEADING INNOVATIVE AUTHORITY** protecting and advancing **NATIONAL HEALTH** and **SAFETY**

Mission

- To **wisely regulate** health products
- To **serve** the administration of justice
- To **secure** the nation's blood supply
- To **safeguard** public health

Health Products Regulation Group

To ensure that drugs, innovative therapeutics, medical devices, health-related products, irradiating apparatus and nuclear materials in Singapore are wisely regulated to meet appropriate standards of safety, quality and efficacy

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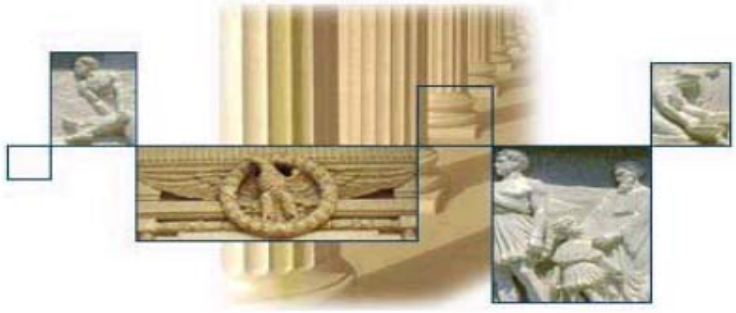
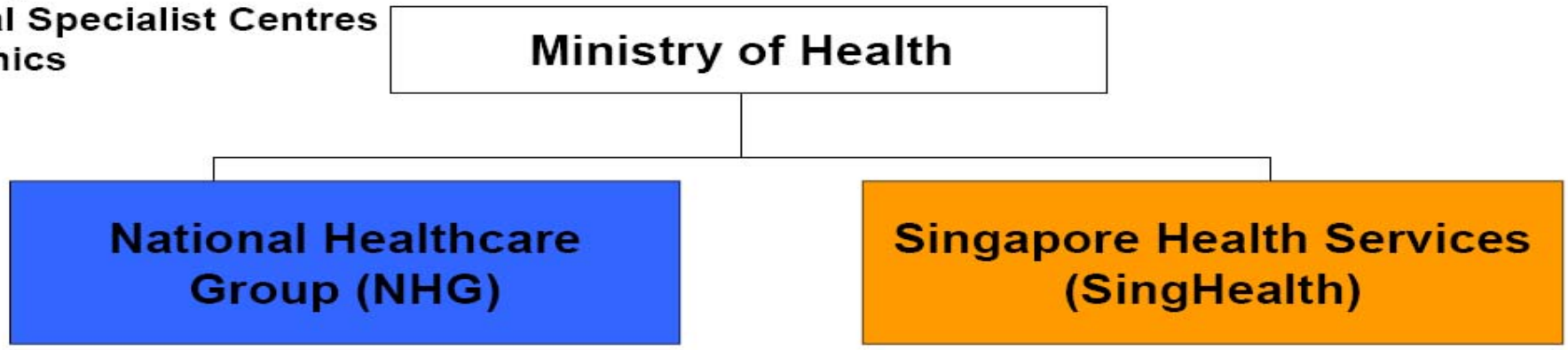
Singapore

- Singapore is a small country (697.1 sq km)
- Total Population: 4.2 million
- Resident Population: 3.44 million in 2003
- Ethnic composition:
  - Chinese : 76.5%
  - Malay : 13.8%
  - Indians : 8.1%
  - Others : 1.6%

Public Healthcare Delivery System

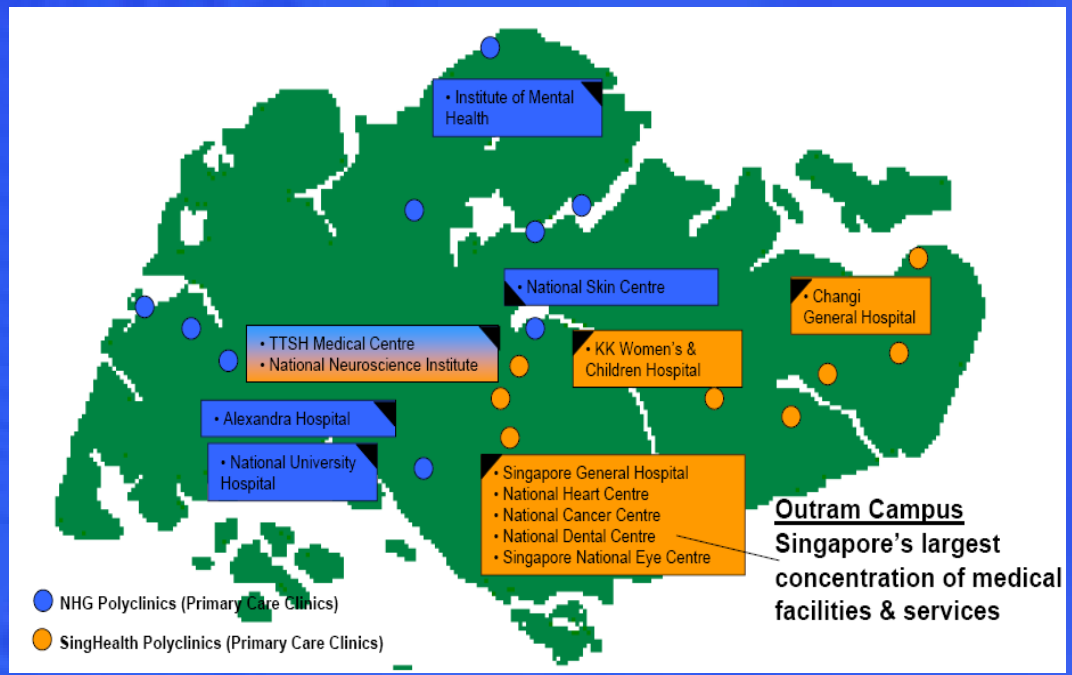
- In Apr 2000, all public healthcare institutions were divided into 2 integrated healthcare delivery networks comprising:
  - Hospitals (tertiary and regional)
  - National Specialist Centres
  - Polyclinics

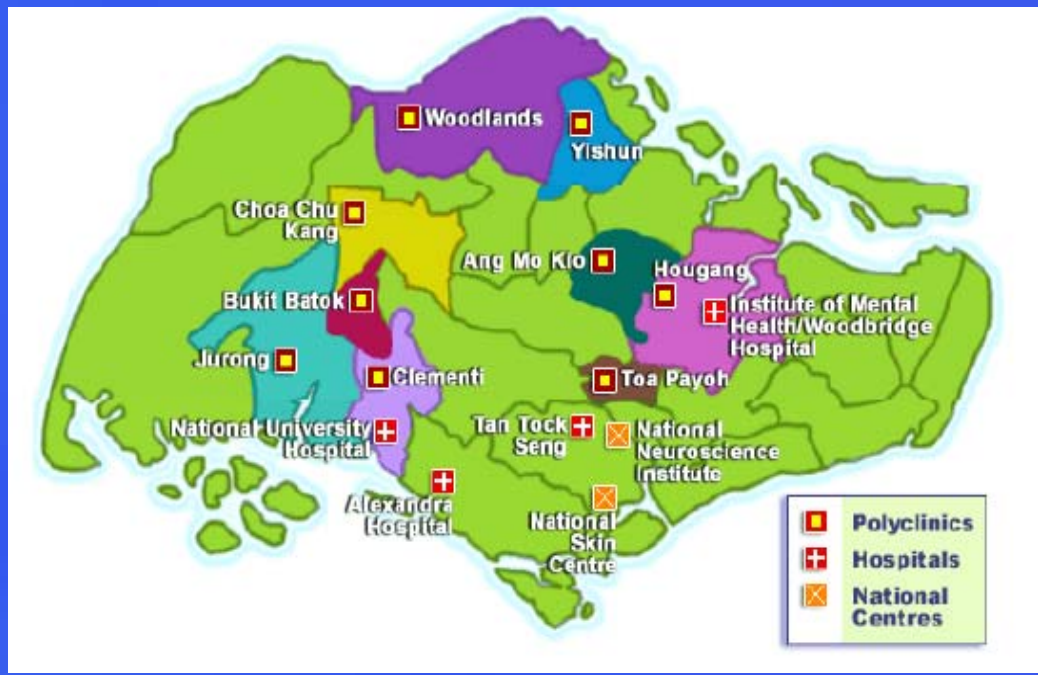




- Aim: Greater integration with better quality healthcare services among public sector healthcare providers
- Receive annual government subvention for the provision comprehensive and affordable healthcare services

Public Healthcare Delivery System





Total: 11,795 hospital beds in 29 hospitals and speciality centres

Ratio of 3.4 beds per 1,000 resident population

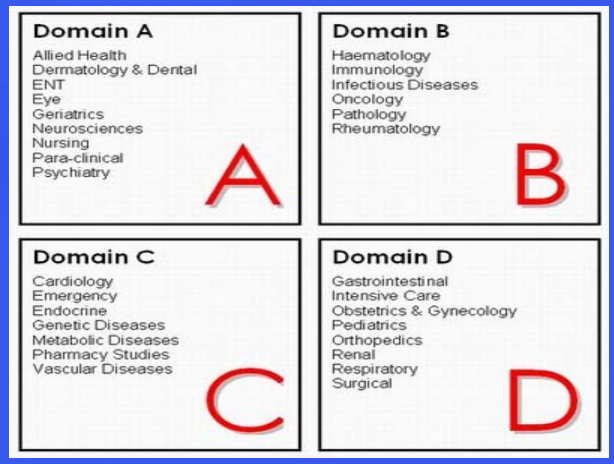
Research Ethics Review Committees

SingHealth
Institutional Review Boards (7 IRBs)

- Review, approve and monitor trials at institution level

National Healthcare Group
Domain Specific Review Board (DSRB)

- Functions like a central IRB for all 6 NHG institutions (Reviews trials under its respective scientific domain)
- Process of accreditation by the Association for the Accreditation of Human Research Protection Program (US)



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Regulation of Clinical Trials in Singapore

1978

Licensing of clinical trials, establishment of the CT Regulations & the Medical Clinical Research Committee (MCRC*)

1998

Implementation of SG-GCP, revision of CT Regulations

* MCRC: External advisory committee that reviews and advises HSA on trial approvals and related matters

Clinical Trial Oversight - Regulatory Basis

Legislation for oversight of clinical drug trials :

- Medicines Act (Chapter 176, Sec 18 and 74)
- Medicines (Clinical Trials) Regulations
- Singapore Guideline for Good Clinical Practice (SG-GCP, adapted from ICH E6 on GCP)

All clinical drug trials conducted locally have to comply with these standards

Current Framework for Clinical Trials

- Parallel Submission to both IRB & HSA
- Ethics and regulatory review and approval timelines ~ 4-6 weeks
- The Health Sciences Authority issues the regulatory approval in the form of a Clinical Trial Certificate
- CTC validity: 2 years and specific for each study protocol, each PI and site involved in the study
- The Licensing Authority for clinical trials under the Medicines Act is CEO HSA

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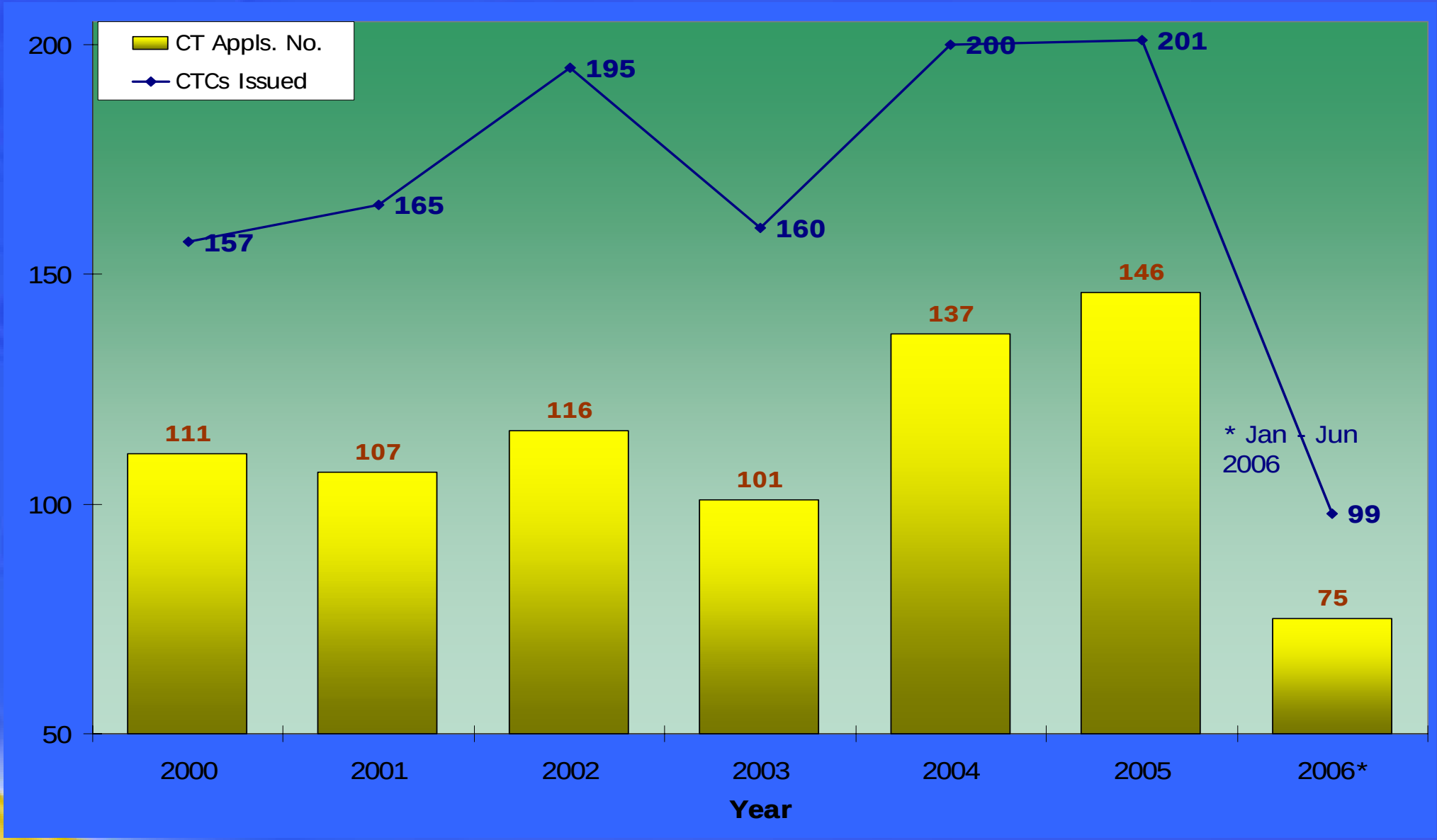
Number of Clinical Trial Certificates

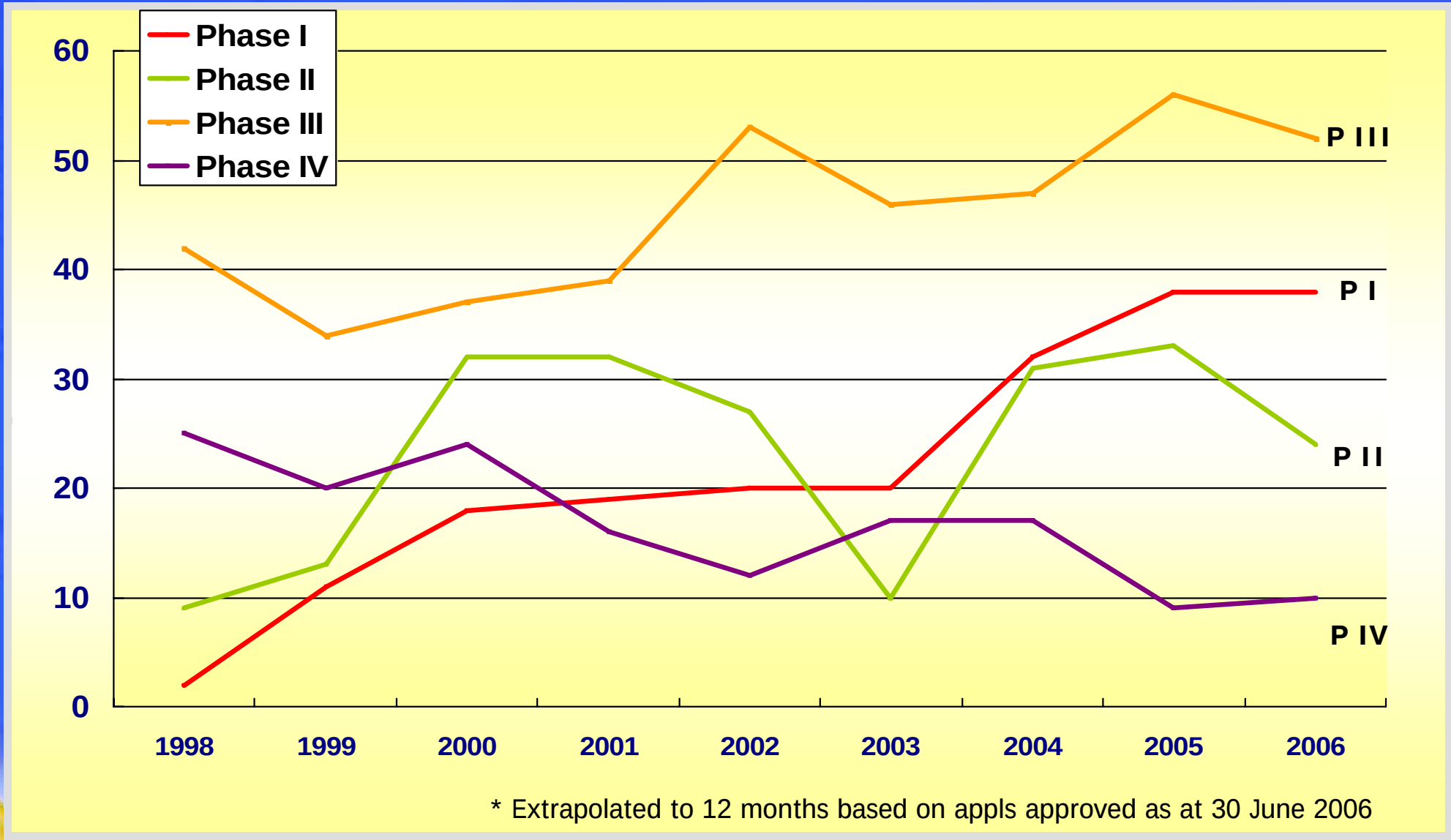
Phase	2000	2001	2002	2003	2004	2005	2006*
I	21	19	20	24	31	44	20
II	44	50	52	19	49	50	16
III	63	68	97	91	88	90	56
IV	29	28	26	26	32	17	7
	157	165	195	160	200	201	99*

** Jan-Jun 2006*

No of CT Applications & CTCs Issued

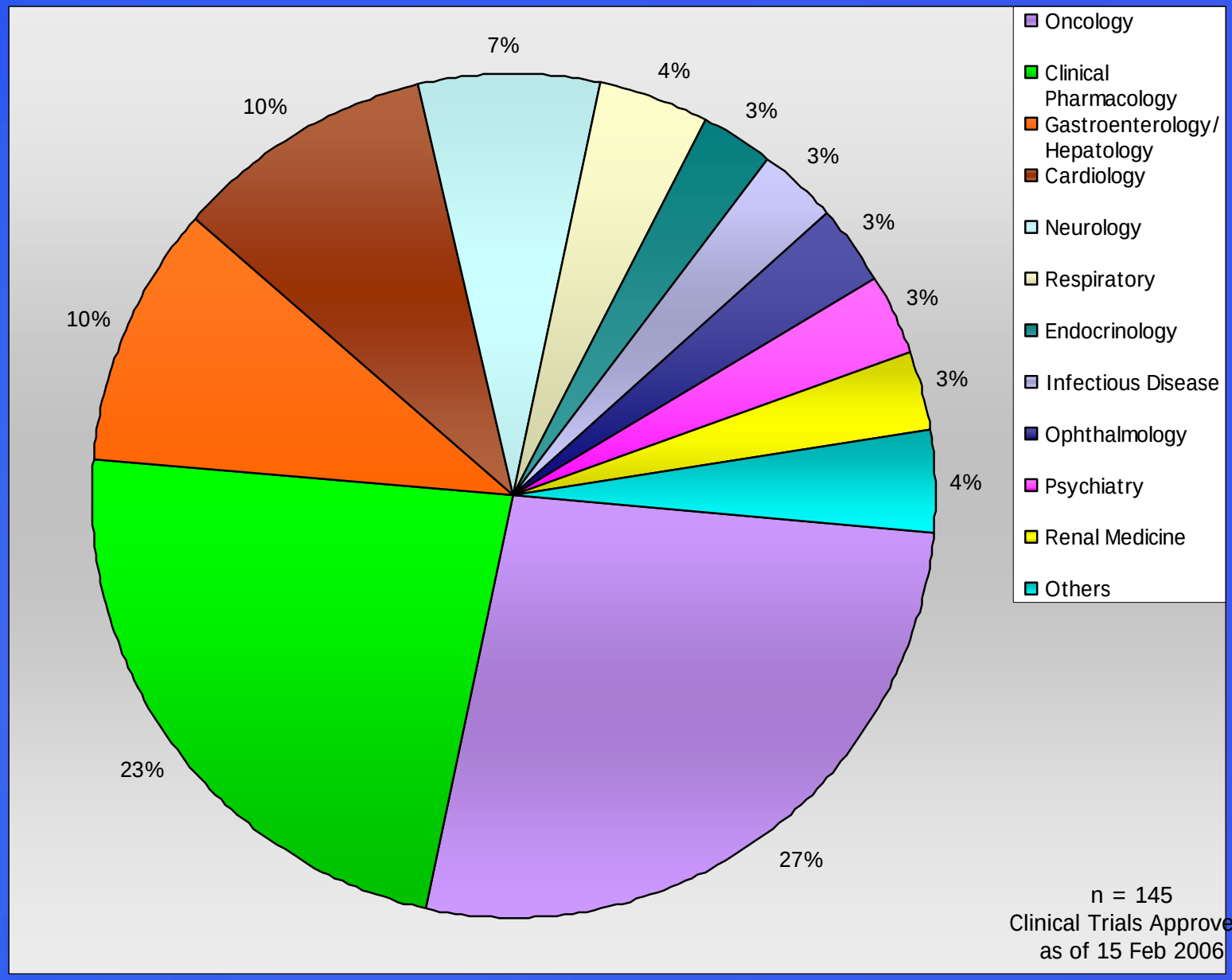


No of Approved CT Applications

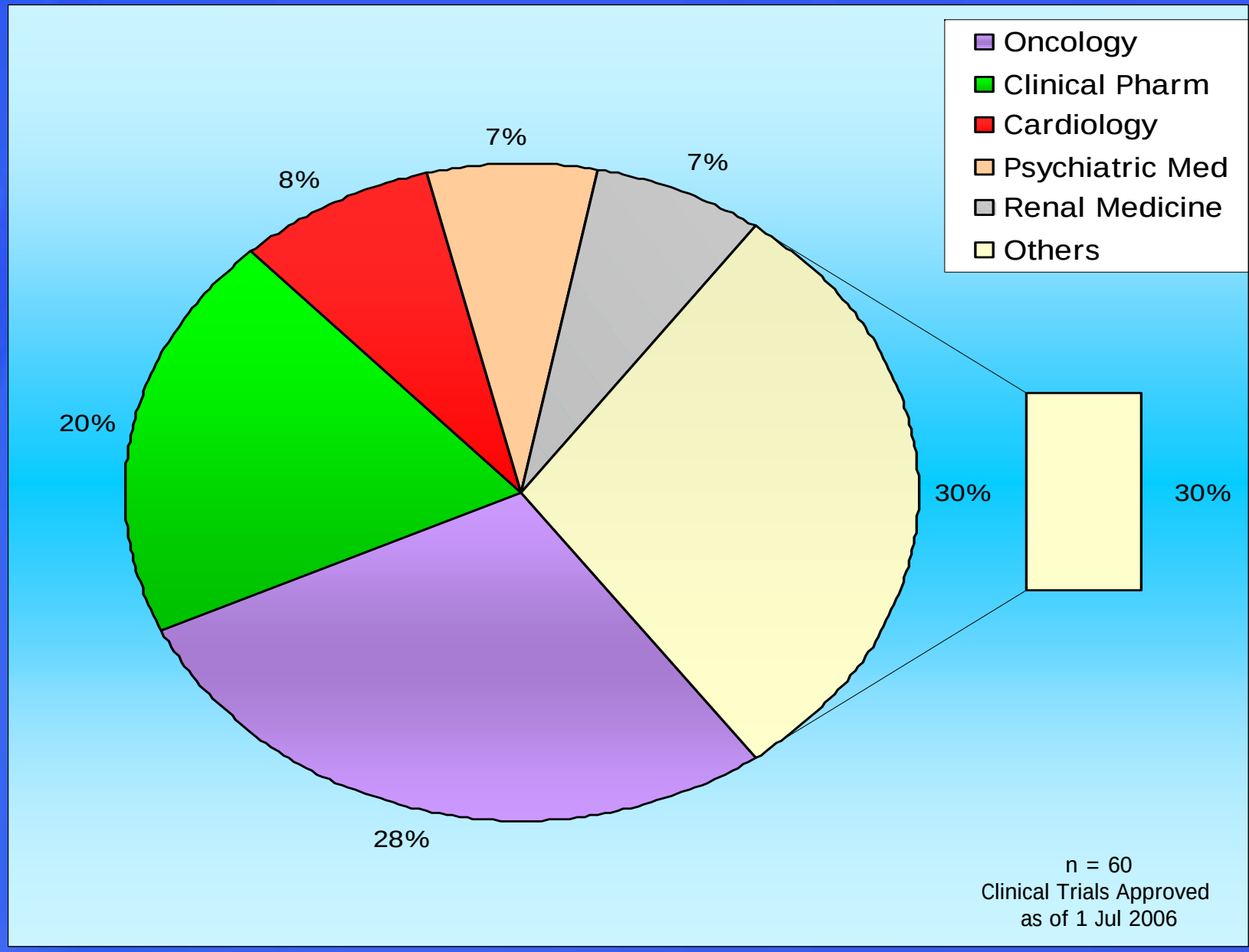


* Extrapolated to 12 months based on appls approved as at 30 June 2006

Clinical Trials Therapeutic Areas (2005)



Clinical Trials Therapeutic Areas (2006)



Clinical Trial Trends

Strong growth of early phase studies with the establishment of Phase 1 units in Singapore:

- Lilly–NUS Centre for Clinical Pharmacology (National University of Singapore)
- Pfizer Clinical Research Unit (Singapore General Hospital)
- CGH – Clinical Trials Research Unit (Changi General Hospital)
- NUH – Clinical Trials Unit (National University Hospital)

Clinical Trial Trends

Reasons for Growth of Early Phase Research

- Early phase studies require small subject numbers and can be completed over a shorter period in a single site
- Availability of dedicated resources and facilities providing the full spectrum of scientific and technological expertise
- Singapore's Biomedical Sciences initiative is key in enabling MNC companies to set up dedicated phase I centres in Singapore and to conduct their drug development programme
- Singapore will continue to support more of such studies to complement this strategy in knowledge-driven research

Clinical Trial Trends

- Strong research interest in Oncology & Hepatitis B Clinical experts/key opinion leaders to conduct these studies well. Excellent cancer research centres focusing in early drug trials, cancer pharmacology, cancer genetics, anti-angiogenesis and cancer endemic in Asia

- Multinational or global trials sponsored by pharmaceutical companies/CROs: 70-80%

- Multinational or global trials to support NDAs to major regulatory agencies: 50-60%

- Bridging studies are not required for local drug registration because of market size and difficulty in identifying a homogenous population

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Vision

Singapore – The Biopolis of Asia

An International Biomedical Sciences Cluster Advancing Human Health Through the Pursuit of Excellence in Research & Development, Manufacturing, and Healthcare Delivery




Basic, Translational & Clinical Research → Product & Process Development → Pilot & Commercial Manufacturing → Regional HQ & Shared Services → Healthcare Delivery

EDB SINGAPORE

Agency for Science, Technology and Research SINGAPORE

Research Infrastructure

Biopolis: Clustering Biomedical Sciences R&D

Phase 1

- All 5 BMRC Research Institutes
- Corporate labs
- S$500 million
- 2 million sqft with additional 300,000 sqft for Phase 2

Biopolis Shared Facilities

- Scientific Services
- Core Services
- General Amenities
- Animal Facilities

EDB SINGAPORE

Agency for Science, Technology and Research SINGAPORE

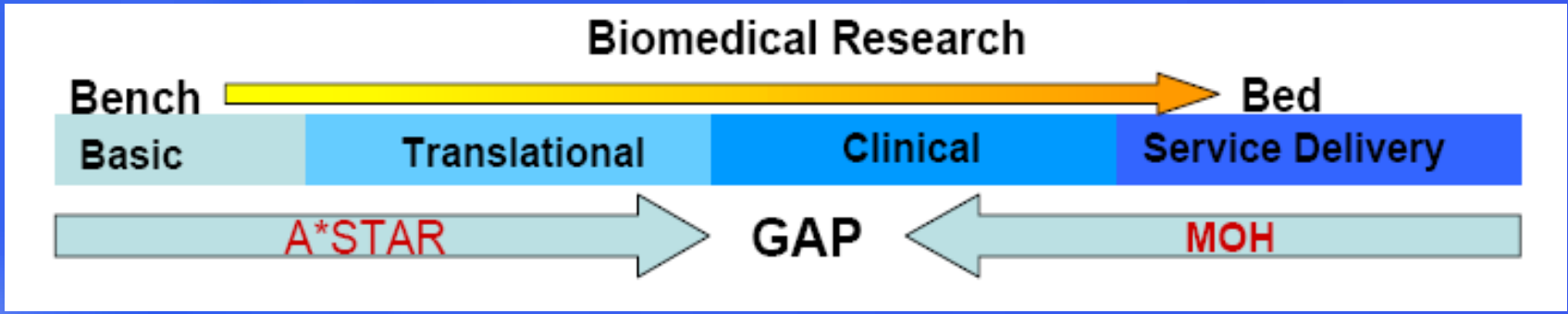
Biomedical Sciences Initiatives

Direction for R&D and Life Sciences

- Leverage existing platforms including A*STAR to tighten integration across healthcare institutions
- Develop key research areas of strategic interest
- Recruit effective research leaders

GAP

- Enhancing regulatory framework
- Develop human capital
- Establish research infrastructure



Biomedical Sciences Initiatives

Sunday Times 30 July 2006

TOP OF THE NEWS

$1.5b to add muscle to biomed sector

► Daryl Loo

NEARLY $1.5 billion will be pumped into Singapore's biomedical sciences sector over the next five years to boost health-care standards and clinic research capabilities.

Announcing the latest package of funding last night, National Research Foundation chairman Tony Tan said the next challenge will be to develop "bench to bedside" research that will see the fruits of this work making its way into mainstream medicine.

"Research will not merely generate high-cost new treatments that only benefit a few rich foreigners. Rather, it will help us develop new treatments and clinical procedures that benefit all Singaporeans," Dr Tan told a group of doctors from KK Women's and Children's Hospital last night.

He was speaking at the hospital's annual lecture and dinner, held at the Marriott Hotel.

Having spent the last five years building up biomedical research institutions, there has been "some success", Dr Tan said.

The sector generated $18 billion in manufacturing output last year and contributed about 5 per cent to the gross domestic product (GDP).

The next step is to "translate our basic biomedical science discoveries into more downstream drugs, methods and therapies".

This "bench to bedside" research requires first developing a group of clinical scientists and investigators here who are capable of carrying out the work, he said.

To that end, the Ministry of Health (MOH) will let more of its doctors do stints in clinical research, while trainee doctors at the National University of Singapore (NUS) and the upcoming Duke-NUS Graduate Medical School will devote more effort to Science, Technology and Research (A*Star).

Developing research capabilities is "critical" for Singapore to maintain its health-care premium against rising regional cost competition, Dr Tan added.

Countries like Thailand, India and China are increasingly offering "First World medical capabilities at Third World prices, much lower than Singapore", he said.

To maximise limited resources, Singapore will focus on areas in which it already has an advantage over regional competitors, including oncology, eye diseases, infectious diseases and the development of medical devices.

The Health Sciences Authority's ability to evaluate new treatments and drugs will also be strengthened.

The high-level, inter-agency Biomedical Science Executive Committee, responsible for leading the biomedical research effort, will also have its line-up changed to reflect the increased role that the Health Ministry is now playing.

MOH Permanent Secretary Yong Ying-I will head this committee jointly with its current chairman, A*Star chief Philip Yeo, Dr Tan said.

The 13-member committee will meet next month.

Said Ms Yong: "Success in our biomedical science efforts will help to establish Singapore as a leader not only in scientific and medical research, but also in medical tourism and industry development.

"This will ultimately improve the quality of health care for Singaporeans."

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- Research, Innovation & Enterprise Council

  Advises the government on national research strategies
- National Research Foundation

  Looks into funding long-term research in strategic areas
- S$1.5 billion (£$112 billion YEN, 0.95 billion USD) over next 5 years

Biomedical Sciences Initiatives

Priorities for strategic research programmes for next 5 years (2006 - 2010) for the Research, Innovation & Enterprise Council:

- To build up core R&D capabilities in strategic areas
- To attract and develop a significant concentration of talent to sustain a critical mass of advanced research activity
- Overall shift towards upstream basic scientific research and early phase clinical research to complement Singapore's strategy in translational research
- To develop Singapore as the best location in Asia for scientific proof of concept in man

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Expanding Regulatory Roles

- Controller & Regulator

- Nurturer & Facilitator

- Convenor & Aggregator

Changing Regulatory Paradigms

To facilitate global development:

- **Wise Regulation**
  - Science based & appropriate knowledge application

- **Regulatory Balance**
  - Risk based & relevant use of regulatory tools
  - Protecting public health & expediting access to new medicines

- **Increasing International Collaboration**
  - Sharing of information, expertise & best practice

HSA
Health Sciences Authority

Thank you