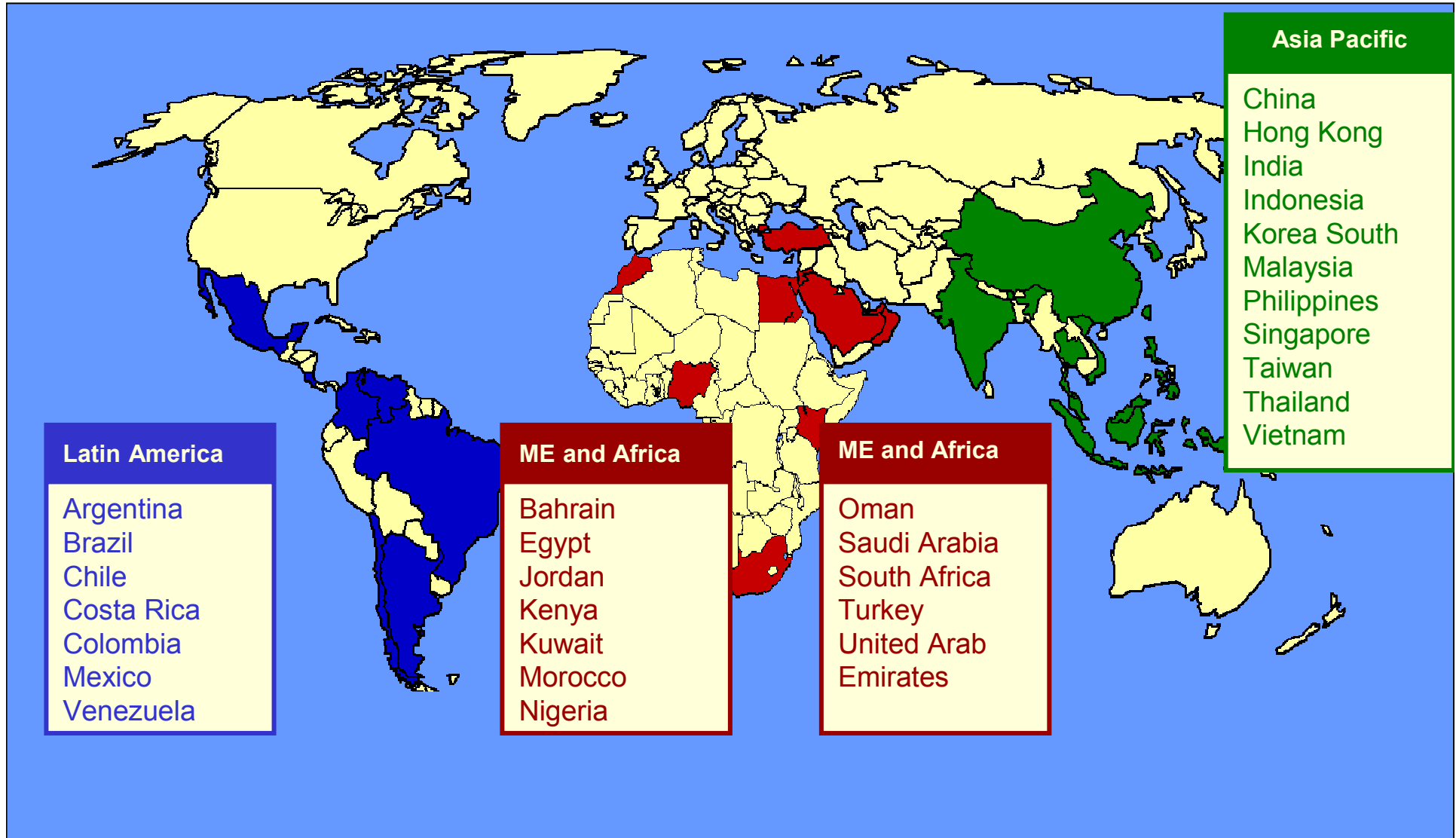


Policies that may lead to the development of innovative capacity including Regulatory Systems

The Changing Regulatory Environment in the developing countries of the Regions of Asia-Pacific, South America, Africa & the Middle East

DICUSSANT at WHO Workshop
May 30th 2005
Professor Stuart Walker
CMR International
Institute for Regulatory Science

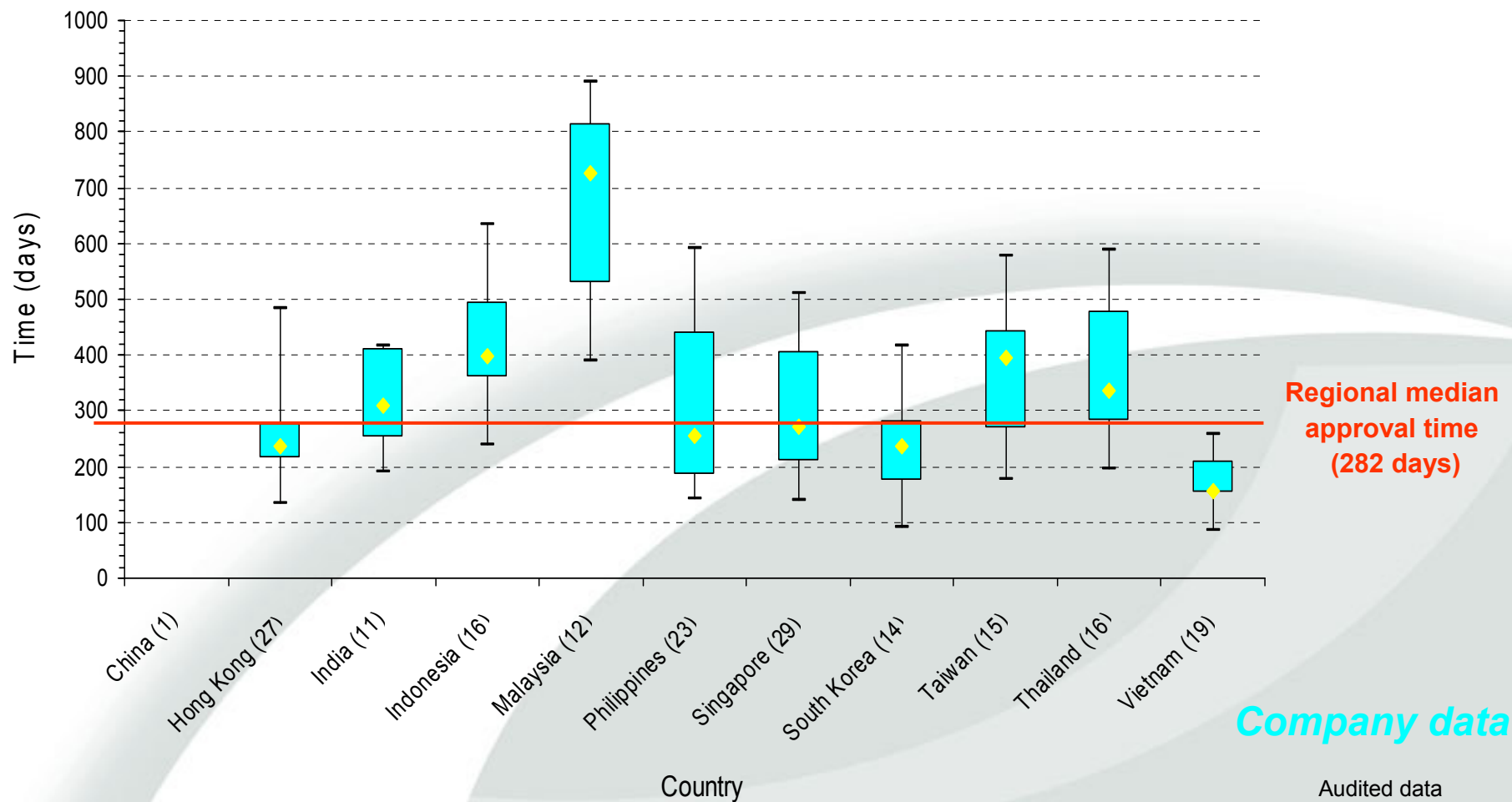
CMR Institute Global study



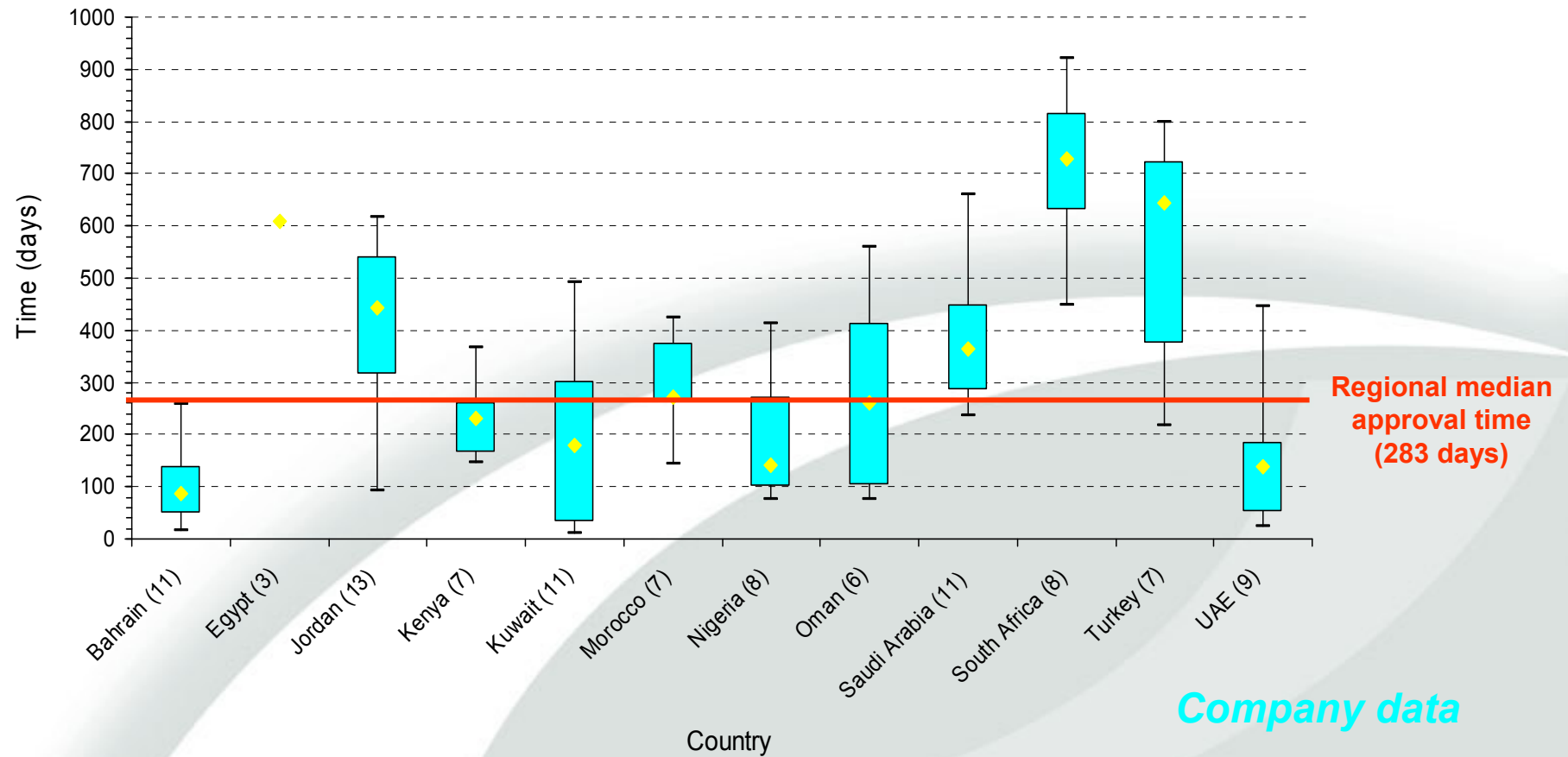
Methodology & Scope of the Study (Ten Companies & Thirty Authorities)

- **Regulatory review & process**
- **Regulatory status in other countries & influence on the review**
- **Transparency of the review process**
- **Application procedure and data requirements**
- **Requirement for Local clinical trials**
- **Policy and perceptions by Industry & Authorities**

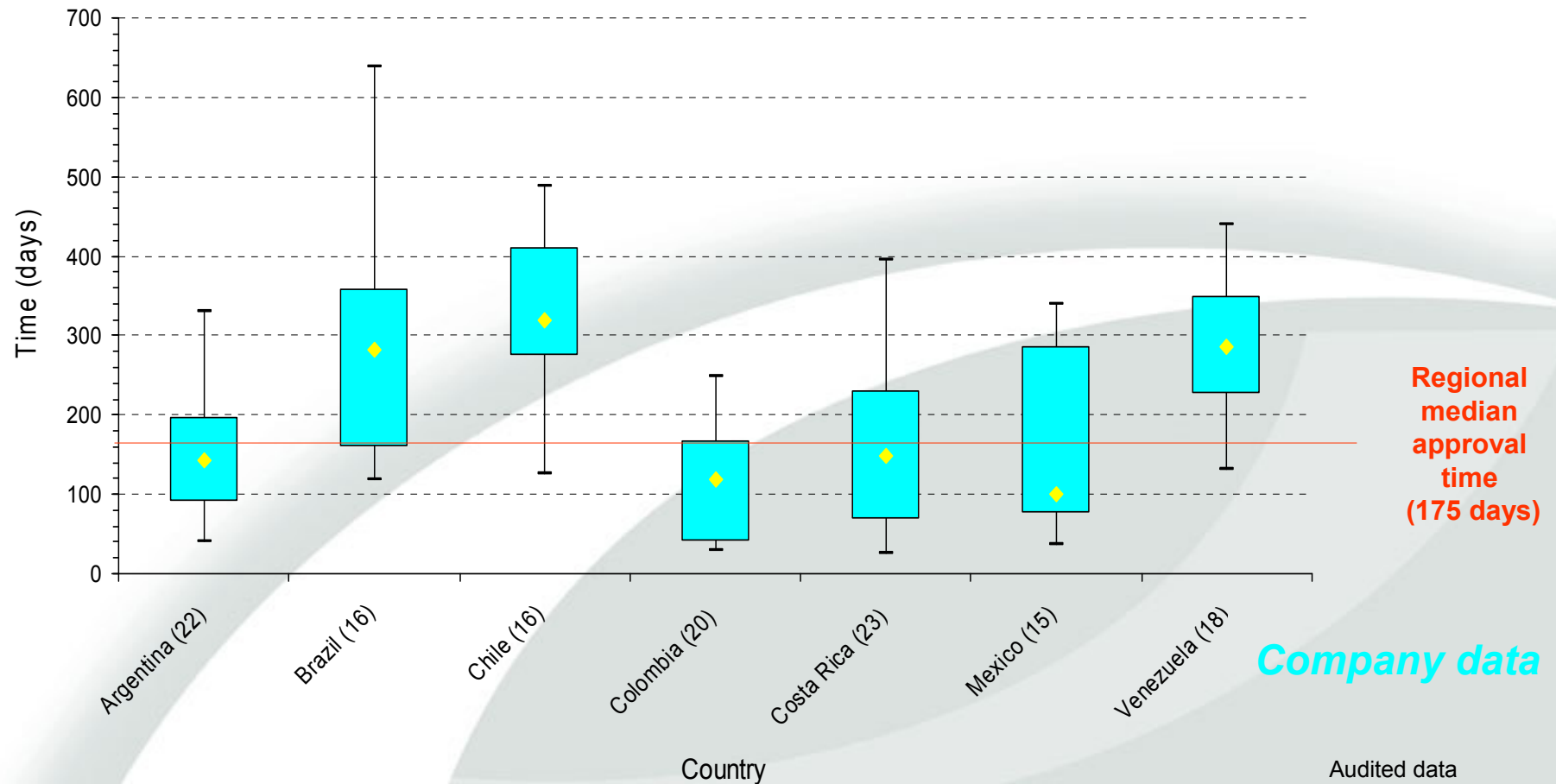
Asia-pacific Region: Regulatory approval times for NASs submitted and approved between 2001 and 2003



Africa & Middle-East Region: Regulatory approval times for NASs submitted and approved between 2001 and 2003



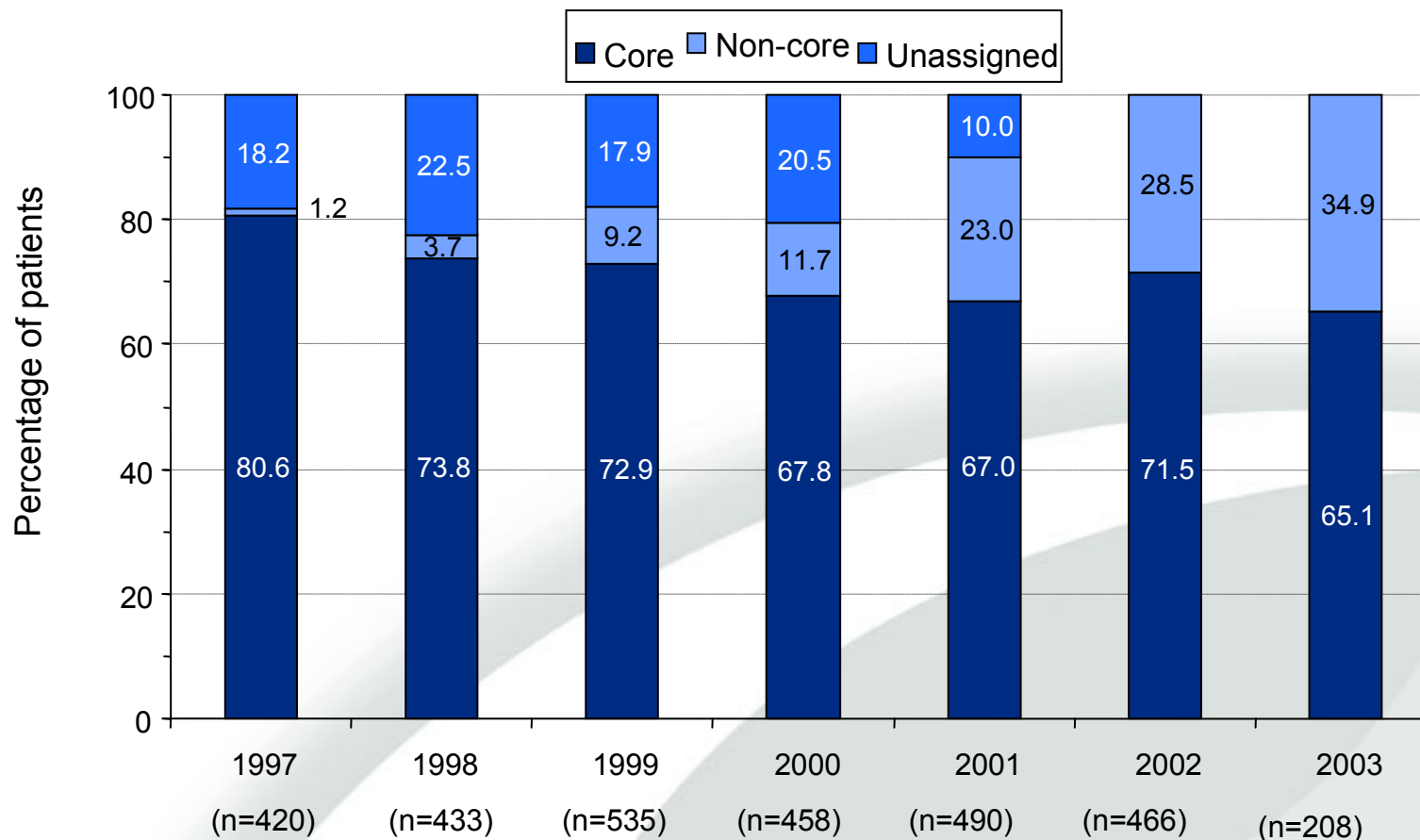
South America Region: Regulatory approval times for NASs submitted and approved between 2001 and 2003



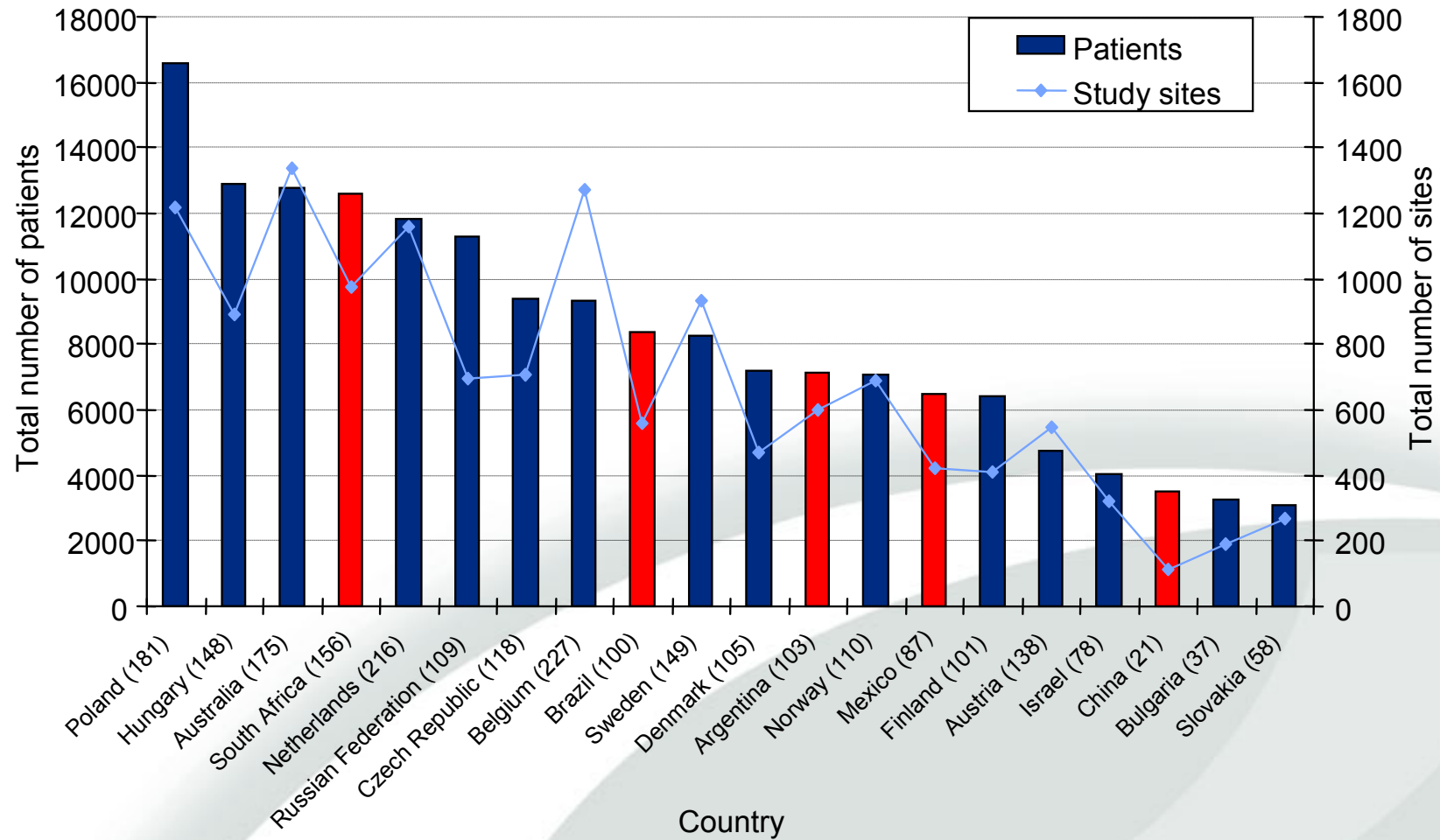
Scope of the Study

- 
- **Regulatory review**
 - **Regulatory status in other countries**
 - **Transparency of the process**
 - **Application procedure and data requirements**
 - **Local clinical trials**
 - **Policy and perceptions**

Percentage of patients enrolled from core and non-core countries between 1997 and 2003



Data are shown for Phase II (including Phase Ip) and Phase III studies where patient enrolment was completed in the year specified and the patient number is available . n = percentage of patients in each group. (n) = the number of studies in the year for a consistent cohort of 20 companies that supplied data each year between 1997 and 2003.



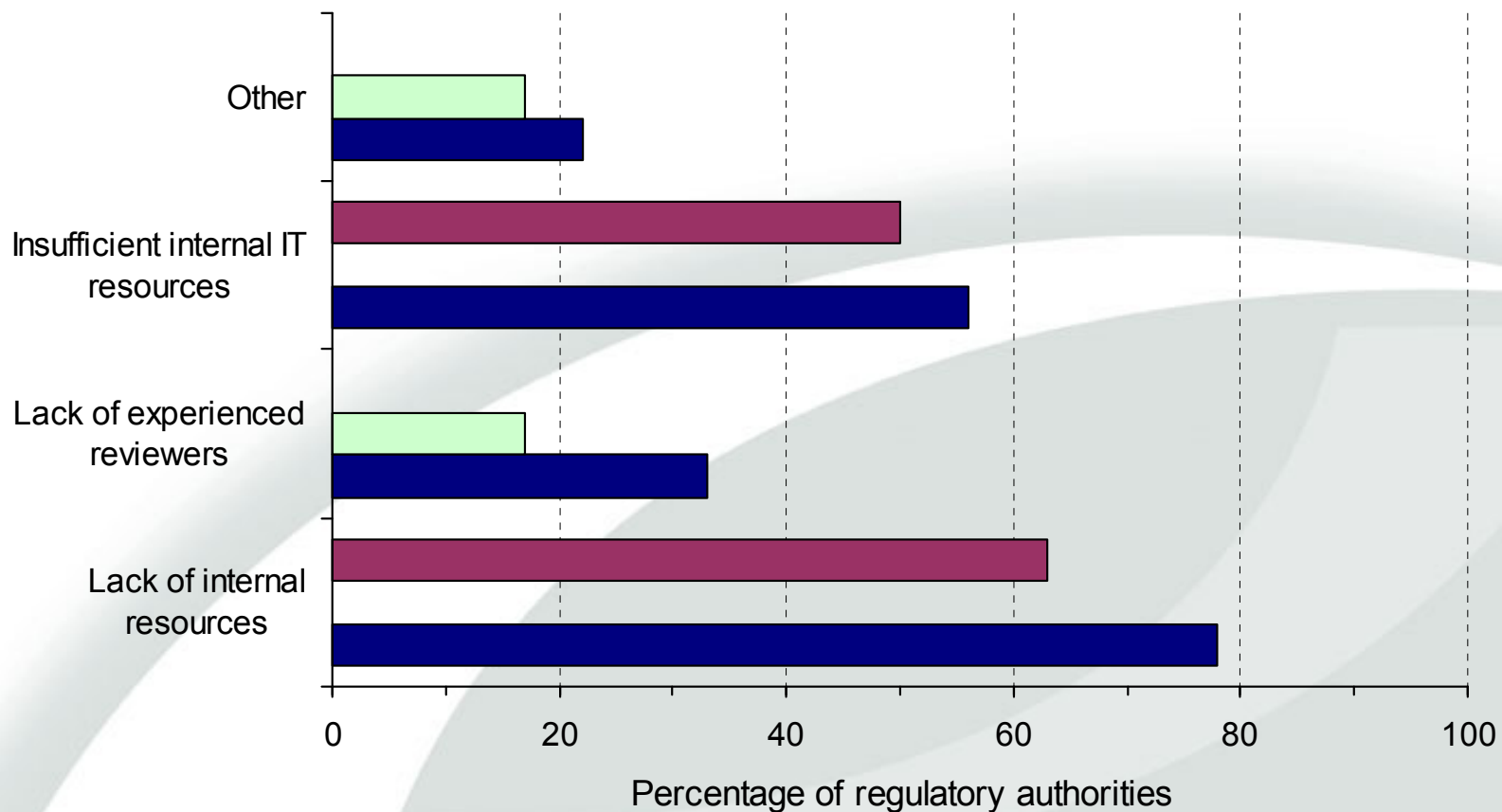
Total patient and site numbers in the top 20 non-core countries where enrolment was completed between 2001 and 2003

Scope of the Study

- 
- **Regulatory review**
 - **Regulatory status in other countries**
 - **Transparency of the process**
 - **Application procedure and data requirements**
 - **Local clinical trials**
 - **Policy and perceptions**

Authorities' perception of internal factors that cause delay to the timely access of patients to new medicines

■ SE Asia (n=9) □ Latin America (n=6) ■ Middle East (n=8)



Authority data

Conclusions: Patients' Access to Medicines

- **Regulatory Review Times**
 - Very variable, what are the reasons for the fourfold differences? Sharing of information on Review Process could lead to best practice.
 - Opportunities for improving Centralised procedures as in Middle East to maximise use of resources
- **Recognition of appraisals in other countries (CPP)**
 - This can conserve resources and reduce duplication of effort
 - Timing of Certificate of Pharmaceutical Product can cause delays of up to a year if at submission
- **Intellectual Property Protection**
 - Essential for future innovation but some concerns about data protection could lead to company delays in registering new medicines?

Conclusions: Patients Access to Medicines

- **Transparency & Application tracking**
 - Increasing adoption of electronic methods
 - International trend towards greater transparency
- **Local clinical trials**
 - Key issue for some countries who now want to be part of Global Drug Development ie India
 - Development of Centres of Excellence with GCP & appropriate Ethical committee review
- **Internal Barriers to patients' access to new medicines**
 - Lack of resources - an international finding across all regions
 - Need for improved training & implementation of other quality measures into Review Process

Policies that may lead to the development of innovative capacity including Regulatory Systems

The Changing Regulatory Environment in the developing countries of the Regions of Asia-Pacific, South America, Africa & the Middle East

DICUSSANT at WHO Workshop
May 30th 2005
Professor Stuart Walker
CMR International
Institute for Regulatory Science