



**ACRO
&
The Scope of a Contract Research Organisations (CROs)**

Dakshina Reddy
Senior Regulatory Manager,
African Clinical Research Organisation (Pty) Ltd

Overview

- An Overview of ACRO
- Outsourcing to a CRO
- When to Outsource
- Global outsourcing model
- Outsourcing considerations
- South Africa as a choice to conduct clinical trials
- Clinical trials in South Africa and Africa

transforming ideas into solutions



An Overview of ACRO

- First South African full-service, BEE, clinical research organisation to manage phase I-IV clinical trials in this region
- Set up through collaboration between LIFElab, and Batswadi Pharmaceuticals
- ACRO services the following sectors:
 - biotechnology sector,
 - donor-funded organisations,
 - non-governmental organisations,
 - research institutions,
 - pharmaceutical and medical device companies, and
 - government.

transforming ideas into solutions



An Overview of ACRO (continued)

- Company focus:
 - infectious diseases such as HIV/AIDS, tuberculosis, and malaria, as well as other diseases affecting various populations in Africa
- Company Commitment:
 - to build capacity across the African continent
 - to develop and strengthen clinical research expertise
 - formation of strategic partnerships for development with a solid base in South Africa and an African focus

transforming ideas into solutions



An Overview of ACRO (continued)

- Services:
 - Preclinical consulting
 - Medical writing
 - Regulatory consulting and implementation
 - Project management and monitoring
 - Medical Monitoring
 - Data management
 - Training

transforming ideas into solutions



Outsourcing to a CRO

- CROs have specialist knowledge across the research environment
- Allows Biotech Company to focus on its expertise
- Reduces Company overheads
- Shortens timelines and costs
- Can share risk

transforming ideas into solutions



When to Outsource

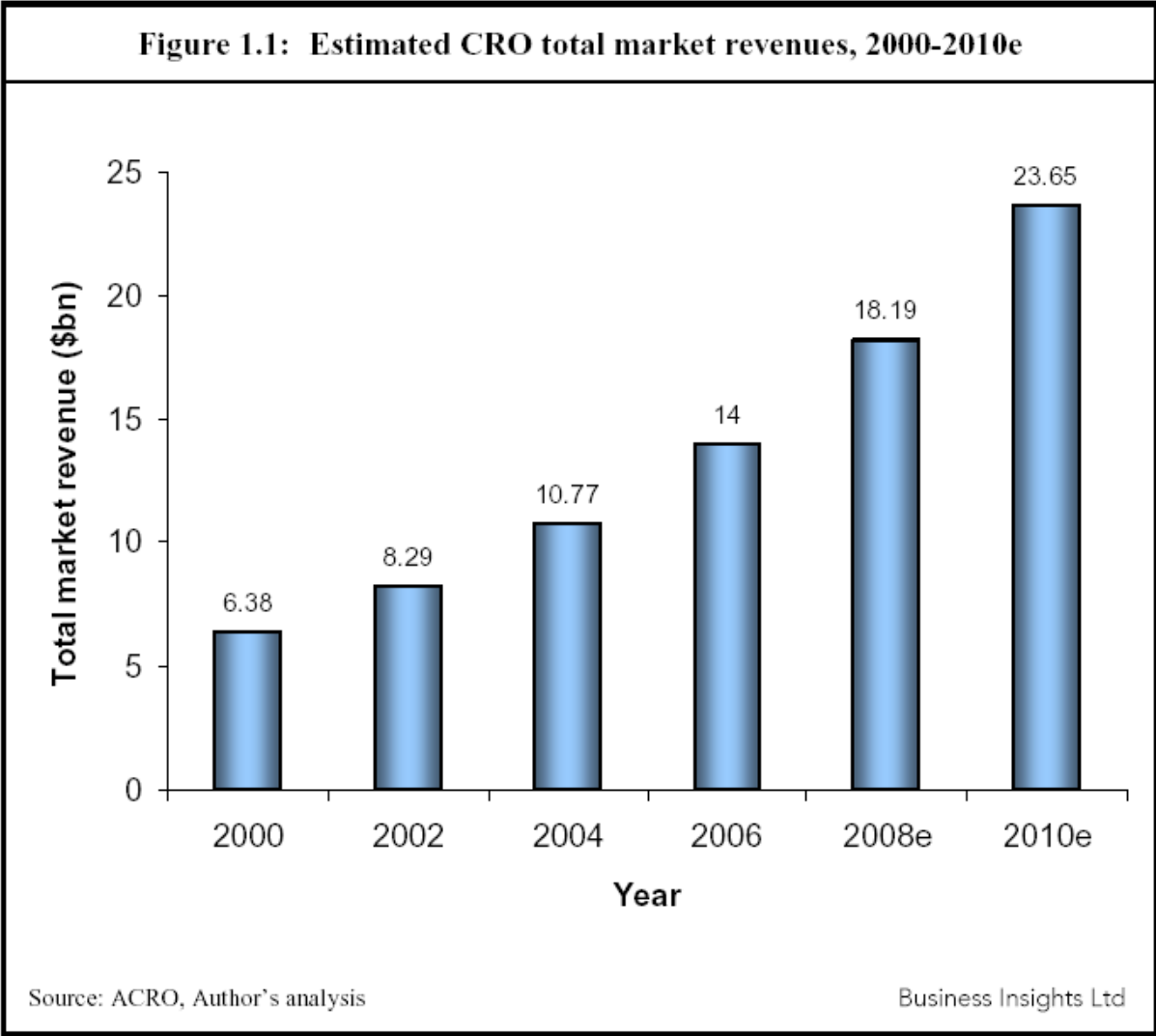
- As early as possible
 - Builds a partnership
 - Encourages comprehensive product strategy
 - Allows expert knowledge of your product and its development

transforming ideas into solutions



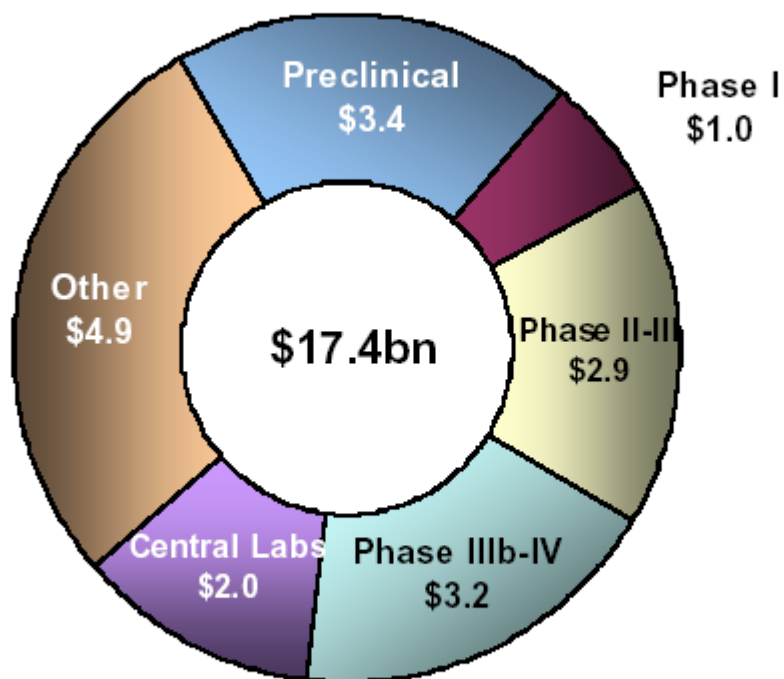
The Global Outsourcing Market

Figure 1.1: Estimated CRO total market revenues, 2000-2010e



The Global Outsourcing Market

Figure 1.4: Global outsourcing market by phase, forecast for 2007

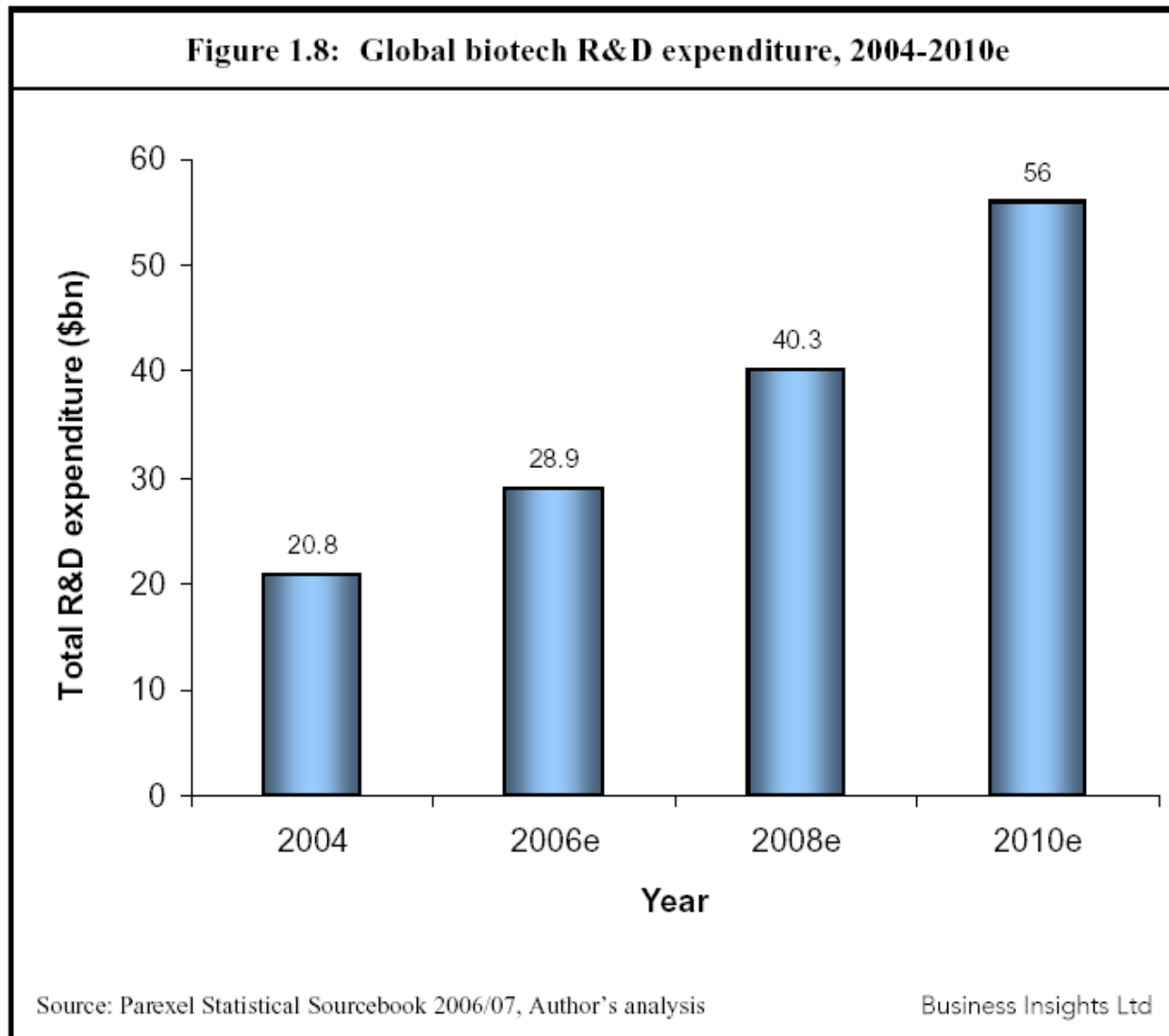


Source: Goldman Sachs Research Estimates, 2005

Business Insights Ltd

solutions

Predicted Global Biotech R & D Expenditure



solutions

Outsourcing Considerations

- Know what you're outsourcing
- Focus on the result
- Work with the CRO
- Be Hands-on without micro-managing
- Manage the relationship
- Clear, comprehensive contracts
- Clear and regular communication

transforming ideas into solutions



South Africa as a choice to conduct clinical trials

- Ethnic diversity
- Socio-economic diversity
- Geographic – southern hemisphere country – prevent delay of trial onset
- Combination of 1st and 3rd world settings resulting in a population that has a vast disease profile and presents with different clinical stages in the disease profile
- Well established infrastructure –road and rail networks, telecommunications
- Well established and experienced ethics committees and regulatory authority
- Adherence to international clinical trial standards, ICH-GCP

transforming ideas into solutions



South Africa as a choice to conduct clinical trials (continued)

- Experienced in conducting clinical trials – experienced investigators and monitors
- South Africa has been recognised to have a high recruitment rate due to sparse distribution of clinics making sites higher recruiters
- Trial patient population not saturated as with most European countries and America – favourable number of either trial naïve or drug naïve patient population
- Competitively priced – ZAR / dollar and ZAR/ Euro exchange rate

transforming ideas into solutions



Clinical trials in South Africa and Africa

- Collaboration with technology experienced partners:
 - IT infrastructure – e.g data management
 - Telecommunication – e.g cellular network coverage in rural areas, data transferral from remote locations
 - Resource collaboration

transforming ideas into solutions



Thank You

transforming ideas into solutions

