

Working Group 2

Building Clinical Trial Capacity

- Objective: Outline a plan of action to address shortcomings in capacity of high burden countries to conduct and monitor clinical trials for new TB therapies

Key Issues Addressed

- What are current global needs for clinical trials capacity?
- What short and medium term plans should be adopted to increase capacity?
- What are major regulatory challenges?
- What can be done to improve lab and infrastructure needs?
- How can partnerships and networks help foster collaboration and build capacity?




TB ALLIANCE
GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT

Global Distribution and Time Required to Ready Site and Lab for Participation in a Phase III TB Drug Registration Trial

	< 6 MONTHS	6 to 12 MONTHS	1 to 2 YEARS	> 2 YEARS
Africa	3	7	8	1
Asia	1	2	1	0
Latin America	1	4	3	0
North America	0	6	0	0
Europe	1	0	0	0
Eastern Europe	0	0	6	0
TOTAL	6	19	18	1




Building capacity for ethics review

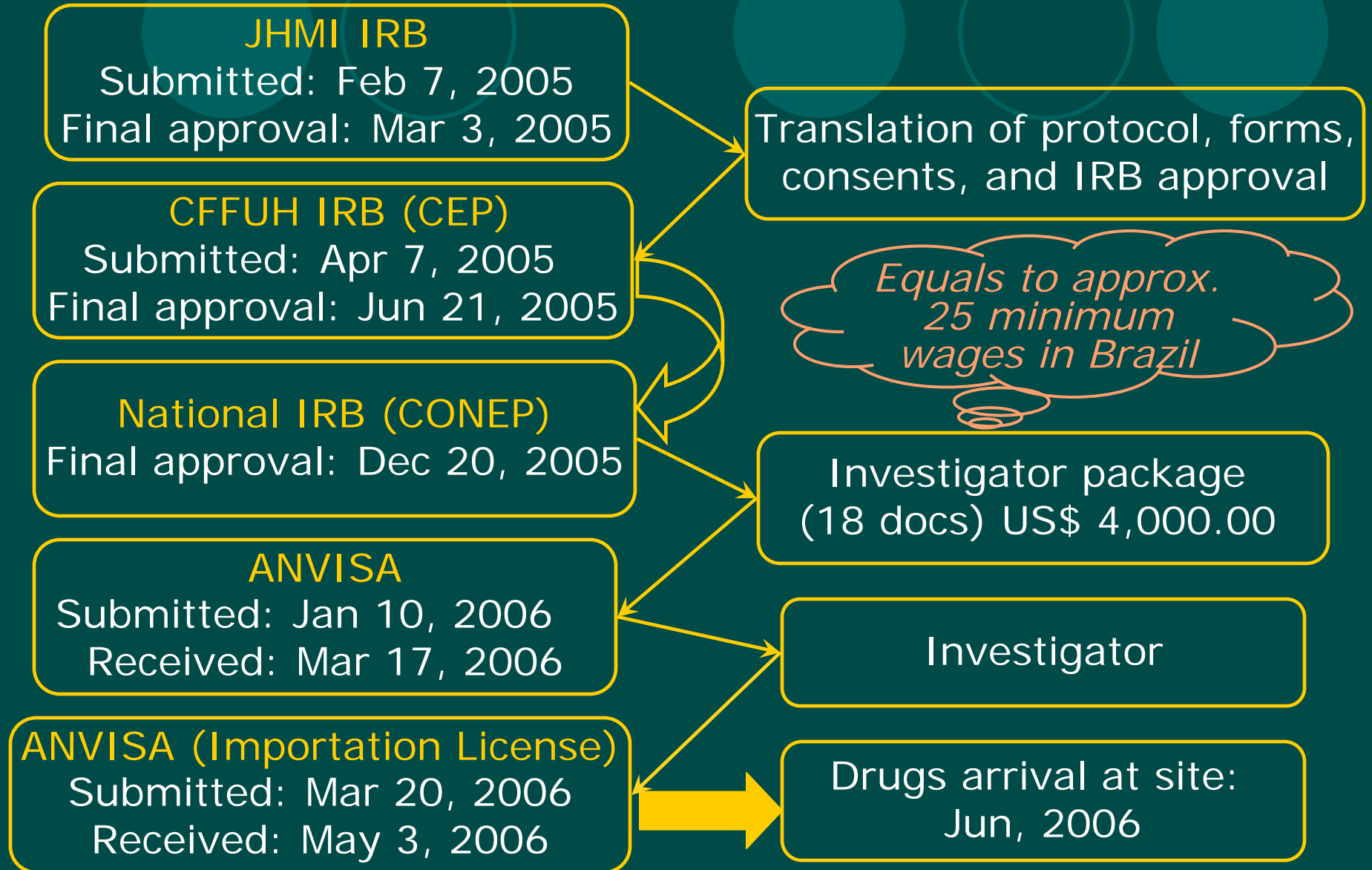
- Formalize ethics training
 - Develop a career structure/training program in ethics, clinical trial monitors
 - Development of a legal framework for Ethics Review committees to intervene where principles of ethics contravened
 - Strengthen linkages between international, regional and national ethics review committees
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Training in research methodology

- Clinical trial methodology
 - Pre-service training, fellowships, mentoring
 - GLP, GCP
 - Regular certification during trial
 - Developing Capacity in statistics, data analysis
 - Clinical trial monitors
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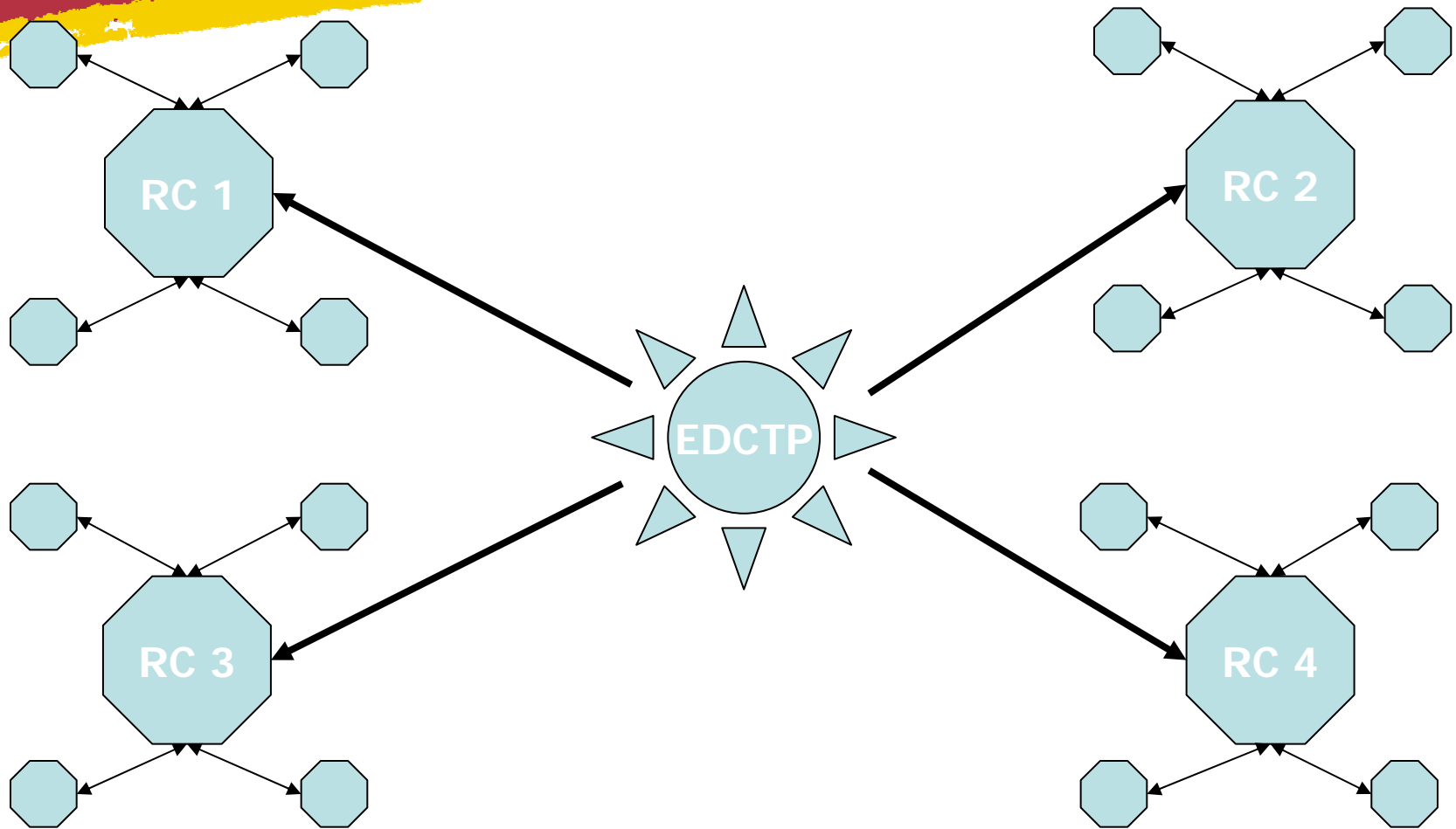
Regulatory Process for Study 28



First enrollment: June 07, 2006 ⇒ **16 months**



EDCTP Conceptual Framework on Nodes of excellence



What is the global need for clinical trials for new TB drugs/regimens?

- 7-10 products in clinical trials in next 3-5 years
- Patients per product:
 - EBA -75
 - Phase 2b – 300-400
 - Phase 3 – 1500 x 2
 - Phase 4 – 2000
 - Total ~5,500
- Cost per patient - >\$10,000
- Total costs - \$550 million

Excludes studies of regimen manipulations, children, HIV+, smear negative, surrogate marker studies, etc.

10 Year Estimates of Costs for Clinical Trials in the Global Plan II

- Phase 1 - \$70 million
- Phase 2 - \$500 million
- Phase 3 - \$1.5 billion
- Total - \$2.07 billion

- Current spending on TB clinical trials = \$20 million

(Funding gap for all drug development activities in the Global Plan II = \$3.6 billion!)

Differing Perspectives on Costs for Clinical Trials

- Product approach - # new products, cost per trial, each company or PDP has its own plan
- Infrastructure approach – need for investment in human capacity, laboratory, ethical/regulatory, community and institutional capability to conduct trials

Addressing Product and Infrastructure Needs

- Network of TB Clinical Trials sites in high burden countries
 - ACTG-style organization with stable funding for clinical staff, education/training, laboratory, data/biostats, ethics, and community engagement
 - TB Platform – able to conduct drug, diagnostic, biomarker and similar trials
- A capable, prepared and adequately resourced clinical trials network will meet product needs more quickly, efficiently and reliably than a product by product approach

How can a TB Network be established?

- Consortium of consortia
- Multiple funders
 - European Commission
 - CDC
 - NIAID
 - BMRC
 - Global Alliance
 - Aeras, CREATE, FIND
 - Pharma
 - Others: no reasonable offer will be refused!

Minimal Costs for TB Network

- 20-25 sites initially
- \$1-2 million per site per year
 - Clinical
 - Laboratory
 - Regulatory
- \$5 million per year for coordinating center (regulatory, biostats, monitoring, etc.)
- Total costs - \$25-\$55 million/year

Place \$\$\$ Here

