Perspectiva de las agencias gestoras de investigación

Carmen Garaizar

Los diversos agentes que intervienen en el desarrollo de un nuevo medicamento varían en sus necesidades porque responden a diferentes concepciones de organización. El sistema sanitario interviene en la fase de investigación clínica del producto, validando su eficacia y seguridad. Responde a un tipo de organización que se aleja en sus objetivos y dinámica interna del mundo académico y empresarial, los cuales intervienen en las fases preclínicas y en la comercialización postautorización.

Las empresas con I+D seleccionan el área temática y el tipo de productos sobre los que investigar, se proveen de los recursos necesarios y evalúan sus resultados científicos y económicos. La I+D es una actividad propia, un "producto" más de la compañía que la desarrolla.

Los centros sanitarios, por el contrario, tienen como objetivo fundamental la provisión de servicios de salud a la población. En ellos surgen dos tipos diferentes de investigación clínica:

1) La investigación médica financiada mediante convocatorias de la Administración Pública, la cual se desarrolla como un "efecto secundario" de la práctica clínica. La "idea" objeto de tal investigación surge del facultativo hospitalario, no de la organización sanitaria. El sistema sanitario ejerce cierto control mediante la priorización de las líneas de investigación y la competitividad de los investigadores para alcanzar unos recursos limitados, gracias a la evaluación externa de sus proyectos.

2) Los ensayos clínicos financiados por la industria farmacéutica son una tarea adicional, no prevista ni particularmente programada en la organización de la actividad asistencial del hospital. El sistema ejerce un control sobre ellos a través de los Comités de Ética, la autorización de los gerentes hospitalarios y la limitación de recursos humanos.

Para coordinar y promover la investigación sanitaria de ambos tipos han surgido fundaciones y agencias públicas en hospitales individuales o para toda una comunidad autónoma. Existen también numerosas asociaciones privadas de facultativos particulares para la gestión de los ensayos clínicos. La función de las primeras consiste en la gestión integral de la investigación, desde la identificación de las necesidades del sistema sanitario y del médico en materia de investigación, hasta la obtención de financiación, gestión de los proyectos y creación de una cultura de investigación en el sistema.

En el caso particular de los ensayos clínicos, las fundaciones y agencias públicas proveen al hospital de un sistema de gestión para la investigación separado de la gestión asistencial, pueden crear unidades específicas para el desarrollo de los ensayos clínicos en los centros sanitarios, canalizar la colaboración de los hospitales con los parques científicos, bioclusters varios, las PYMES biotecnológicas y laboratorios centrales, y con las asociaciones de pacientes. Pero muy especialmente pueden profesionalizar la realización de los ensayos clínicos dentro de los hospitales, encargándose del acortamiento de los tiempos de evaluación y firma del contrato, y de la provisión de recursos al facultativo para que cumpla eficazmente el reclutamiento y el seguimiento de los pacientes acordado. Las fundaciones y agencias públicas podrían aumentar la competitividad de los centros sanitarios (hospitales o atención primaria) como proveedores de investigación clínica.

A continuación se describen las fortalezas y debilidades internas, las oportunidades y las amenazas del entorno, propias del análisis DAFO, en lo que se refiere a la práctica de los ensayos. Se concluye que la "educación y formación" en nuevos medicamentos debiera completarse con la "difusión del conocimiento" dirigido al mundo sanitario, sobre todo en áreas básicas y bioéticas que capacitan al sistema para comprender e incorporar la práctica de los ensayos clínicos como un producto sanitario más de su actividad fundamental. Buena parte de estos conocimientos debieran ampliarse a todo el espectro, desde el paciente hasta las autoridades sanitarias, porque se requiere la aceptación y la colaboración de todos para desarrollar una buena gestión de los ensayos clínicos.

Perspective of the R&D management agencies

Carmen Garaizar

The various agents intervening in the development of a new drug have different needs on account of having different organizational conceptions. The healthcare system intervenes in the clinical research phase of the product and validates its efficacy and safety. It is a type of organization whose objectives and internal dynamics differ greatly from those of academia and industry, which intervene in the preclinical and postauthorization phases.

Companies with an R&D department choose the thematic area and the type of products they are to research, provide themselves with the necessary resources and evaluate their scientific and economic results. R&D is an in-house activity, just another "product" of the company.

Conversely, the primary objective of healthcare centers is to provide healthcare to the population. Healthcare centers feature two different types of clinical research:

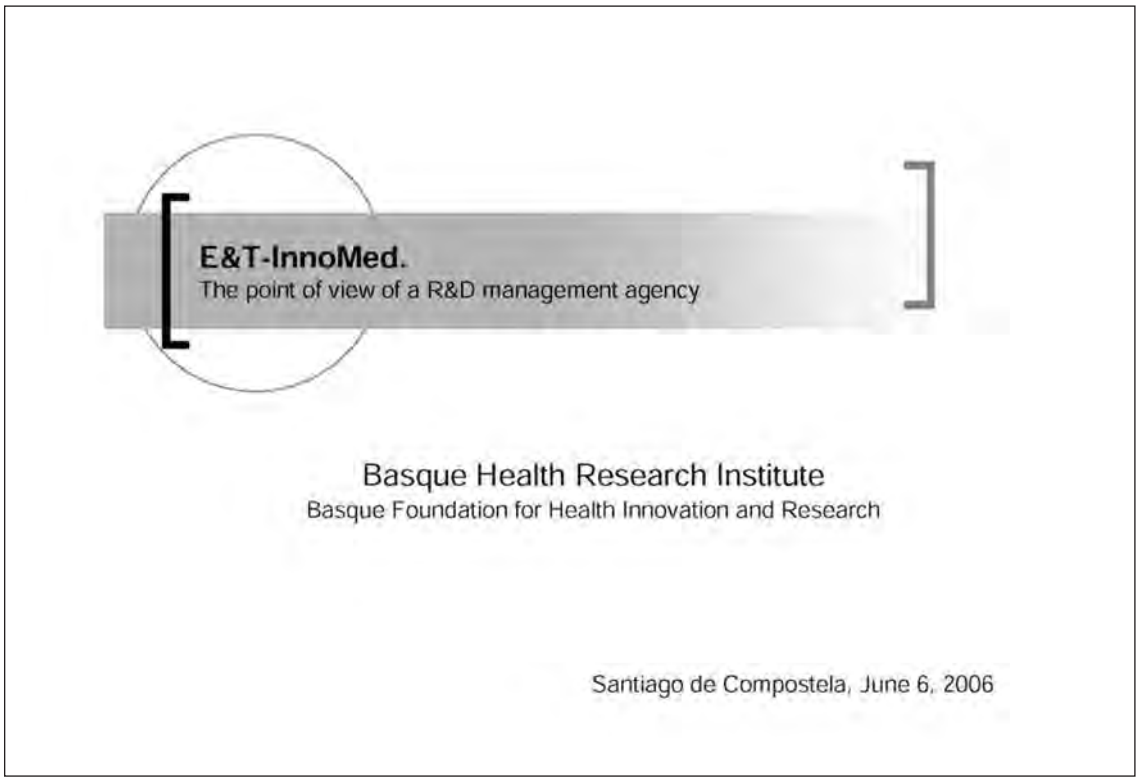
1) Medical research funded by means of public administration calls for research. This research is developed as a "side effect" of clinical practice. The idea to be researched is brought up by the hospital doctor, not by the healthcare organization. The healthcare system exerts some control by prioritizing the lines of investigation and the competitiveness of the researchers to reach limited resources, thanks to the external evaluation of their projects.
2) Clinical trials funded by the pharmaceutical industry, these being additional, unforeseen and not particularly scheduled tasks within the organization of the hospital's healthcare activities. The system exerts control over these trials by means of ethics committees, hospital manager authorizations and human resource limitations.

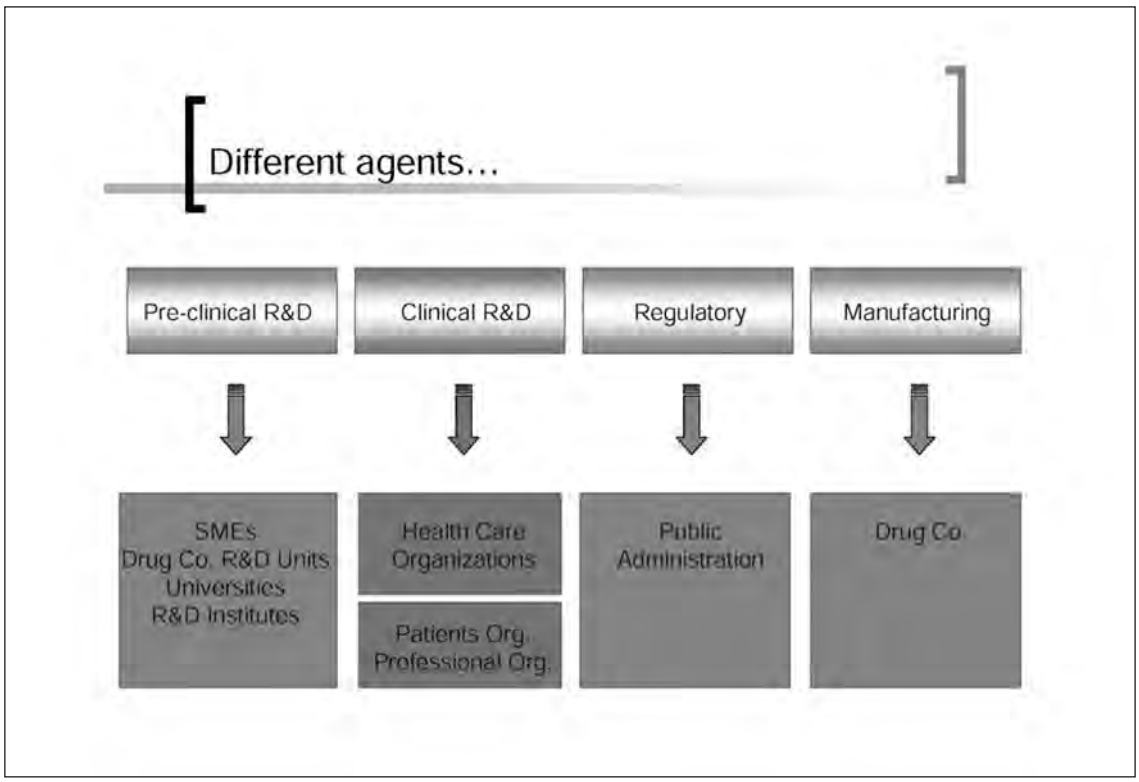
In order to coordinate and foster healthcare research in the above two cases, foundations and public agencies have been created in individual hospitals or for a whole autonomous community. There are also many private associations owned by particular physicians for clinical trial management. The function of foundations and public agencies is the integral management of research, ranging from the identification of research-related needs of the healthcare system and the physician, to the obtention of funding, management of projects, and creation of a culture of research within the system.

In the particular case of clinical trials, foundations and public agencies provide the hospital with a research management system different from healthcare management. They also create specific units for clinical trial development inside the healthcare centers, and channel the collaboration of hospitals with scientific parks, bioclusters, biotech SME's and central laboratories, as well as with patient associations. Most particularly, however, they may professionalize clinical trial performance within hospitals by shortening the terms of evaluation and contract signing, as well as by providing the physician with resources so that he/she may effectively comply with the agreed patient enrollment and follow-up periods. Foundations and public agencies could increase the competitivity of healthcare centers (hospitals or primary care units) as clinical research suppliers.

Inner strengths and weaknesses, as well as outer opportunities and threats (SWOT analysis) in connection with clinical trial practice, are further described from the public healthcare system's point of view. It is concluded that "education and training" in new drugs should be complemented with a "diffusion of knowledge" directed toward the healthcare environment, particularly in basic and bioethical

areas, which enable the system to understand and incorporate clinical trial practice into their main activity as if it were just another health product. A good part of this knowledge should be extended through the whole range, from the patient to health authorities, given that the acceptance and collaboration of all involved is required to achieve a good clinical trial management.


E&T-InnoMed.
The point of view of a R&D management agency
Basque Health Research Institute
Basque Foundation for Health Innovation and Research
Santiago de Compostela, June 6, 2006


Different agents…
Pre-clinical R&D
Clinical R&D
Regulatory
Manufacturing
SMEs
Drug Co. R&D Units
Universities
R&D Institutes
Health Care Organizations
Patients Org.
Professional Org.
Public Administration
Drug Co.

… different needs…

…because of different conceptions

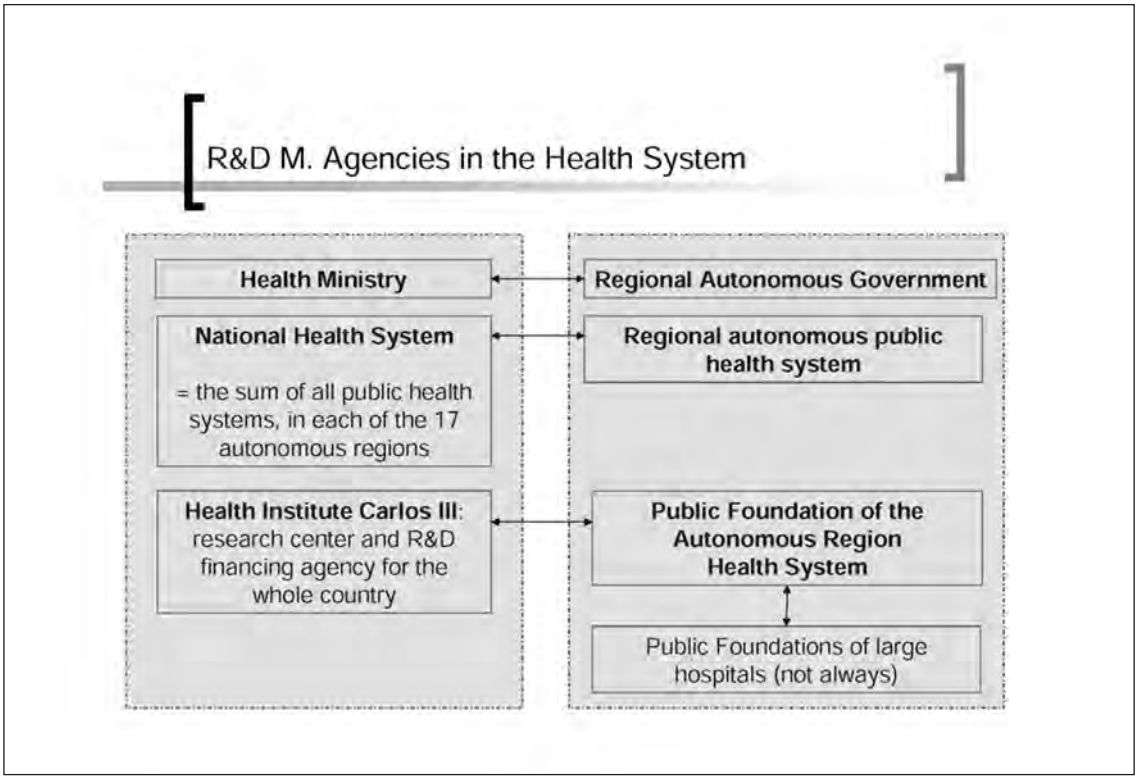
The Co. selects de subject of R&D, provides the means, awaits for retrieval / benefits.

R&D is a product of the Co.

- Basic activity is provision of health services to population
- R&D "idea" is doctor generated, not hospital generated, for projects with public competitive external funding.
  Control mechanisms are: research lines priorization
  resources limitation
  internal and external evaluation
  competitive external financing
- Clinical Trials are 40% of all external funding of hospital R&D
  Control mechanisms are: ethical committee
  hospital manager authorization
  internal resources limitation

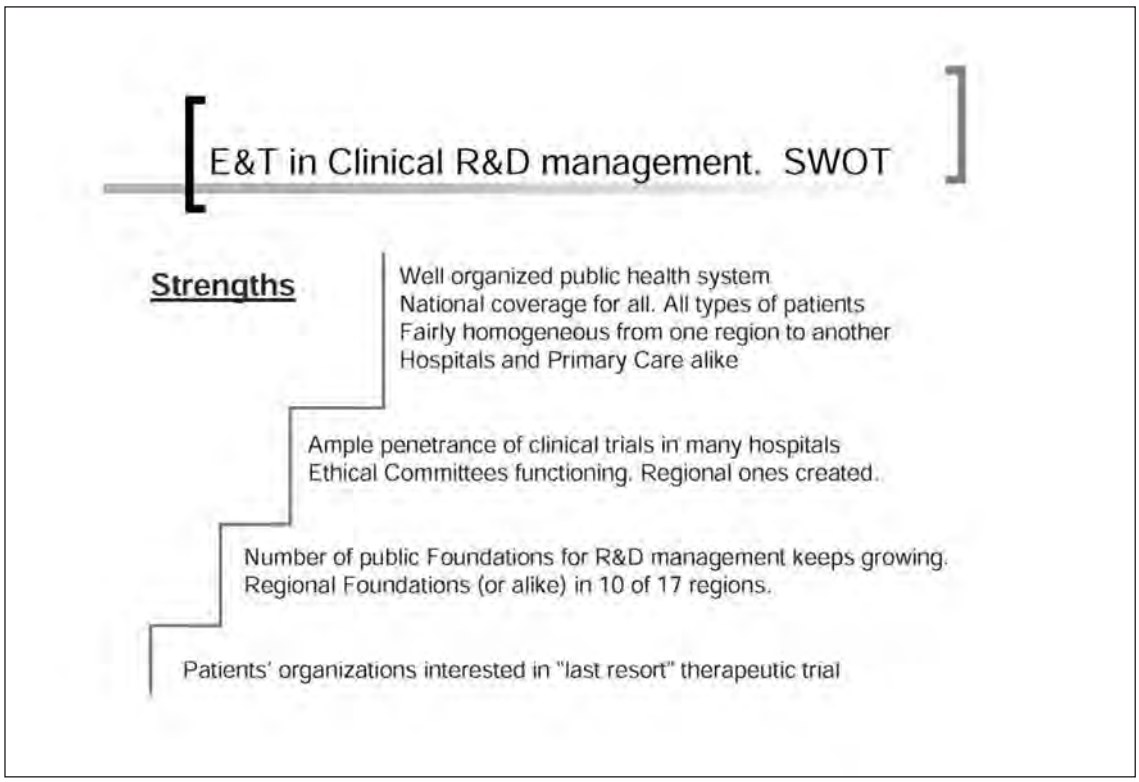
R&D as a "secondary effect" of clinical practice

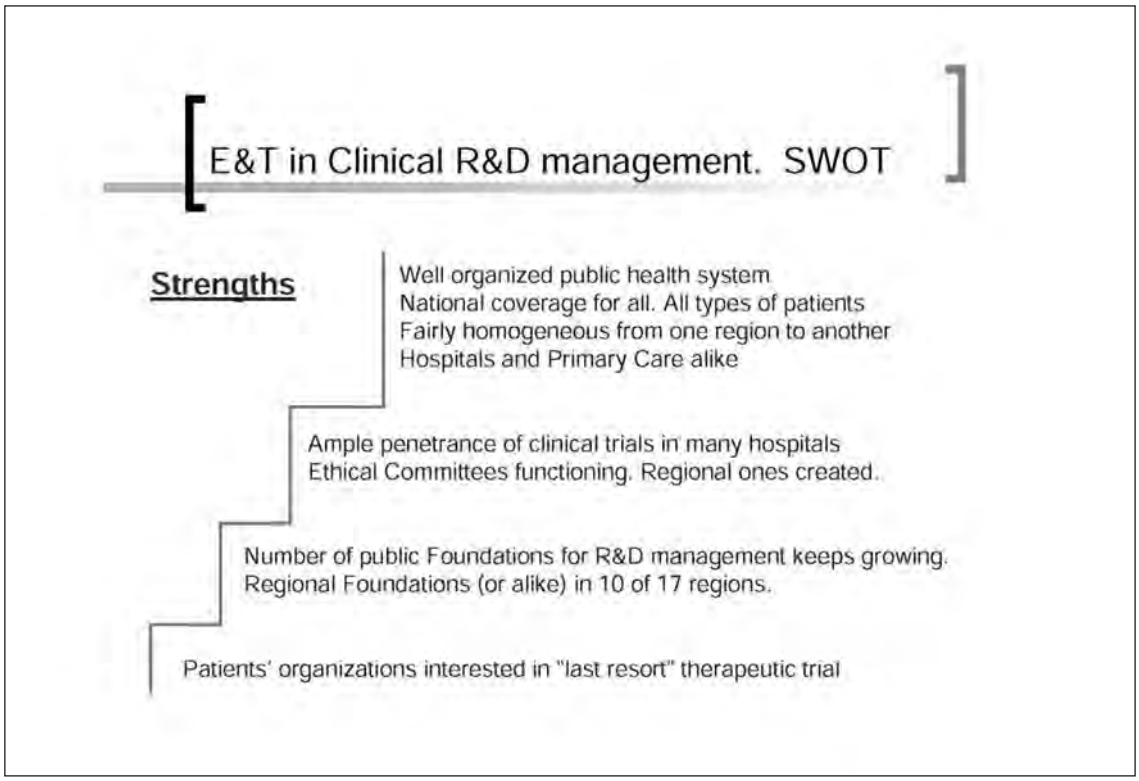
Clinical Trials as an add-on" practice not originally intended

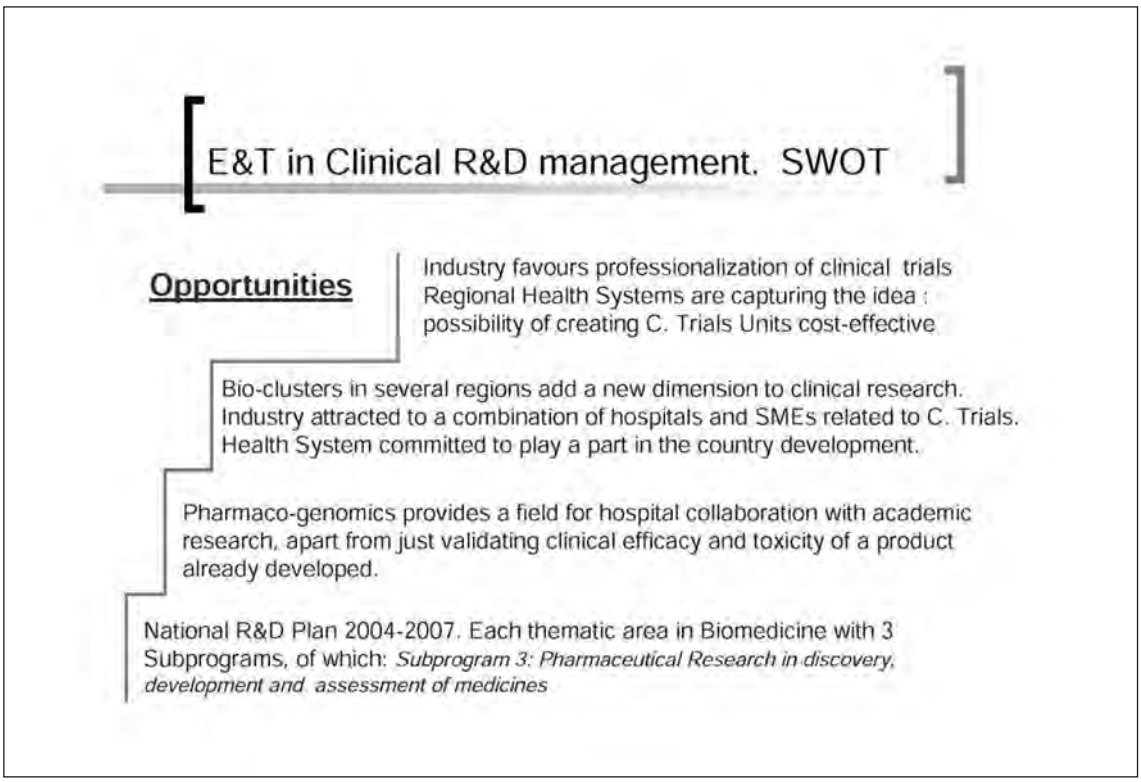

R&D M. Agencies in the Health System
Health Ministry
Regional Autonomous Government
National Health System
= the sum of all public health systems, in each of the 17 autonomous regions
Regional autonomous public health system
Health Institute Carlos III: research center and R&D financing agency for the whole country
Public Foundation of the Autonomous Region Health System
Public Foundations of large hospitals (not always)


Regional and hospital agencies for R&D management
1. Identify the Health System needs on R&D.
For competitive funded research projects (not clinical trials):
2. Register all projects, human and material resources and potential competitive financing agents.
3. Priorization and coordination of R&D among hospitals and agencies
4. Fund raising
5. Support to project development: training, search for partners, couching…
6. Research Programs: human resources, large equipment, clinical trials…
7. Economic-administrative management of projects
8. Outcome evaluation
9. Creating a R&D culture within the system.


As for clinical trials, the regional/hospital agency can:
Provide the hospital with a separated administrative structure for R&D apart from hospital management
Create specialized CT Units within the hospital (CT Coordination Office, Phase I CT Unit, ...)
Participate in Scientific Parks, Regional Bio-clusters, collaboration SMEs, central laboratories, etc. AND patients' organizations
Professionalize clinical research management within the health system
Shorter time for ethical evaluation
Shorter time for hospital contract
MD supported to perform the accorded duty
Hospital (or Primary Care) as a competitive clinical research provider


E&T in Clinical R&D management. SWOT
Strengths
Well organized public health system
National coverage for all. All types of patients
Fairly homogeneous from one region to another
Hospitals and Primary Care alike
Ample penetrance of clinical trials in many hospitals
Ethical Committees functioning. Regional ones created.
Number of public Foundations for R&D management keeps growing.
Regional Foundations (or alike) in 10 of 17 regions.
Patients' organizations interested in "last resort" therapeutic trial


E&T in Clinical R&D management. SWOT
Strengths
Well organized public health system
National coverage for all. All types of patients
Fairly homogeneous from one region to another
Hospitals and Primary Care alike
Ample penetrance of clinical trials in many hospitals
Ethical Committees functioning. Regional ones created.
Number of public Foundations for R&D management keeps growing.
Regional Foundations (or alike) in 10 of 17 regions.
Patients' organizations interested in "last resort" therapeutic trial


E&T in Clinical R&D management. SWOT
Opportunities
Industry favours professionalization of clinical trials
Regional Health Systems are capturing the idea :
possibility of creating C. Trials Units cost-effective
Bio-clusters in several regions add a new dimension to clinical research.
Industry attracted to a combination of hospitals and SMEs related to C. Trials.
Health System committed to play a part in the country development.
Pharmaco-genomics provides a field for hospital collaboration with academic research, apart from just validating clinical efficacy and toxicity of a product already developed.
National R&D Plan 2004-2007. Each thematic area in Biomedicine with 3 Subprograms, of which: Subprogram 3: Pharmaceutical Research in discovery, development and assessment of medicines

E&T in Clinical R&D management. SWOT

Threats

Conflict of interests between main objective of public health systems and that of profit seeking drug developing company

Lack of transparency in providing final results, occult biobanks, marketing policies... Health system distrust.

More efficient hospitals for clinical trials in other countries

Social distrust of ethical and economic interests in trials. The same for manufacturing products away from needing third world countries. Fear of science.

E&T recommendations from this point of view

1. Add "Knowledge diffusion" to Education and Training
2. Create knowledge to provide understanding of what's going on

Knowledge on:	General Biotechonology Pharmaco-genomics Pharmaco-economy, pharmaco-epidemiology Research in health services provision and health policy making GCP, Bioethics Social and economic impact of new medicines Drug industry policies
Knowledge for:	Patients Clinicians: doctors and nurses, hospitals and Primary Care Members of ethical committees Members of Hospital Boards and managers Public R&D management agencies Health System authorities