MINISTERIO DE ECONOMÍA Y COMPETITIVIDAD

30 ANIVERSARIO (1986-2016)

Instituto de Salud Carlos III

Reunión de Trabajo de la Red Española de Ensayos Clínicos Pediátricos (RECLIP)

Madrid, 21 de noviembre de 2016

La Iniciativa de Medicamentos Innovadores 2
IMI 2

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La problemática subyacente

- La I+D farmacéutica se está trasladando fuera de Europa
- La ayuda pública en I+D en Salud en Europa es menor en comparación con los EEUU. Situación estancada.
- Las inversiones privadas en Europa en el sector son mucho más bajas que en los EEUU, y con mayor percepción de riesgo.
- Fragmentación de los esfuerzos de la investigación entre básica, clínica e industria.
- Aumento de los costes de desarrollo de medicamentos, y elevada proporción de fracasos.

Base conceptual

"Deciphering the complexity of human diseases and finding safe, cost-effective solutions that help people live healthier lives requires **collaboration across scientific and medical communities throughout the health care ecosystem**.

Indeed, we must acknowledge that **no single institution, company, university, country, or government has a monopoly on innovation.**"

Sci Transl Med 29 January 2014:
Vol. 6, Issue 221, p. 221ed2
Sci. Transl. Med. DOI: 10.1126/scitranslmed.3008294

‹ Prev | Table of Contents | Next ›

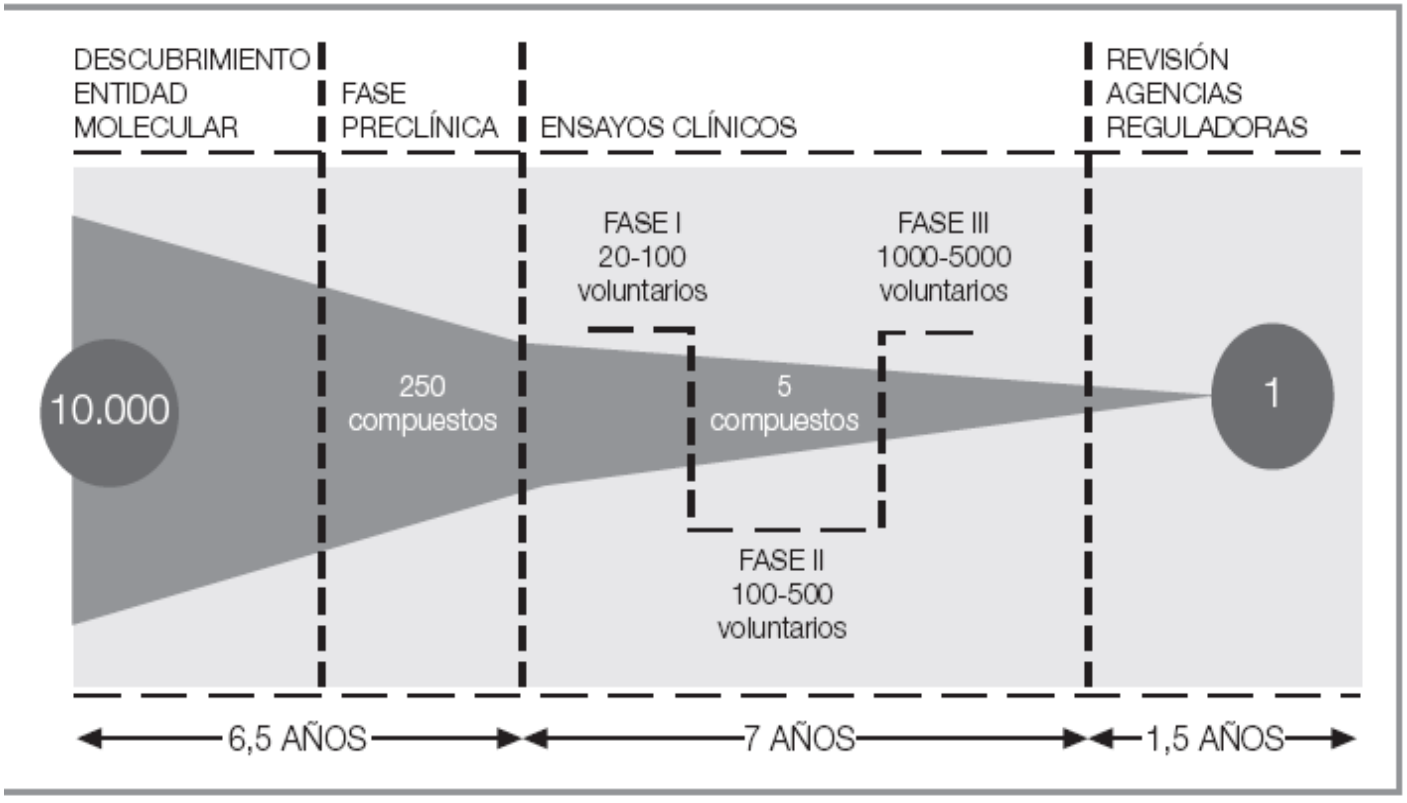
EDITORIAL

DRUG DISCOVERY

Turning the Titanic

Elias A. Zerhouni

Los riesgos del desarrollo farmacéutico



Vida total de la patente: 20 años

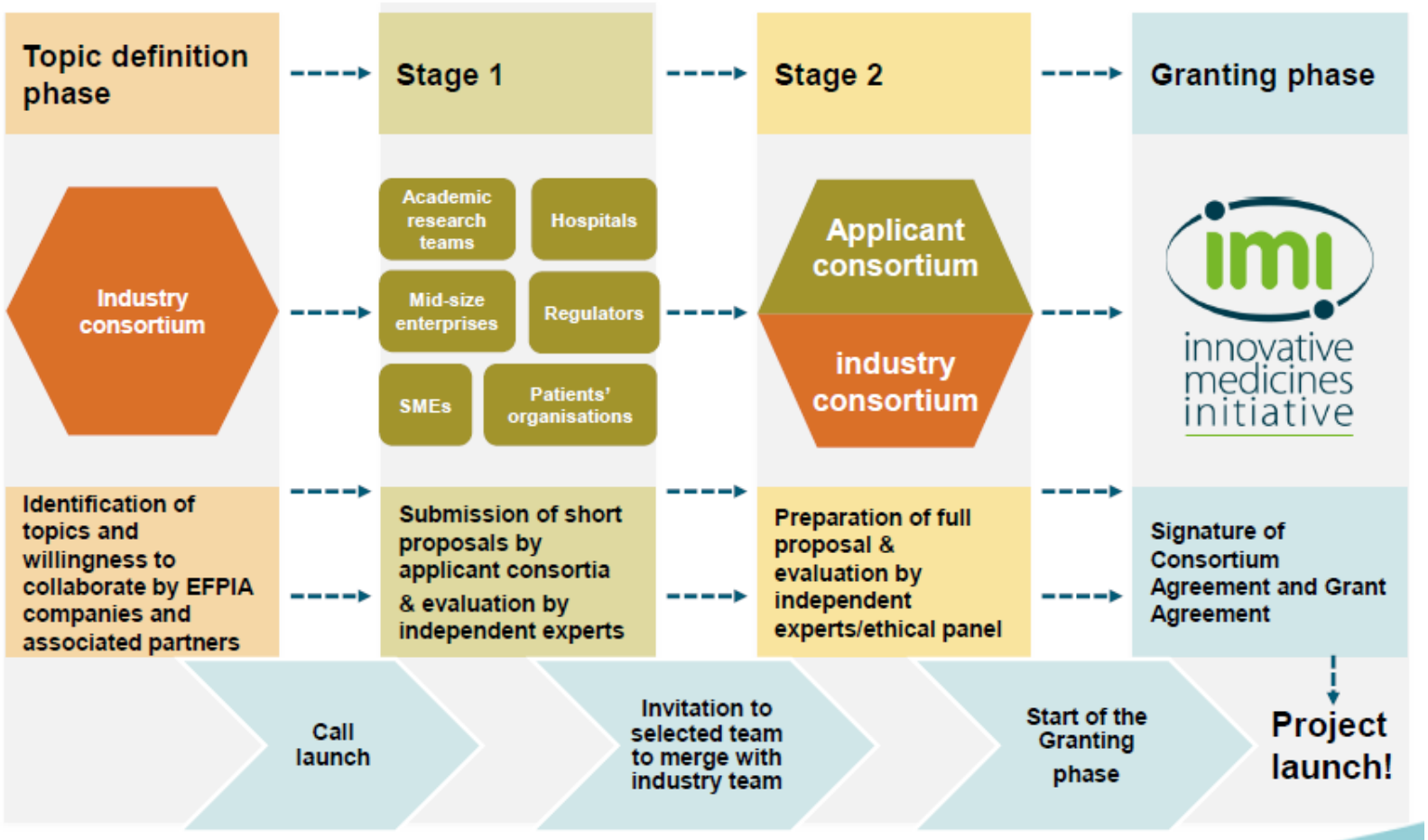
¡5 años para explotación!

La Iniciativa de Medicamentos Innovadores 2

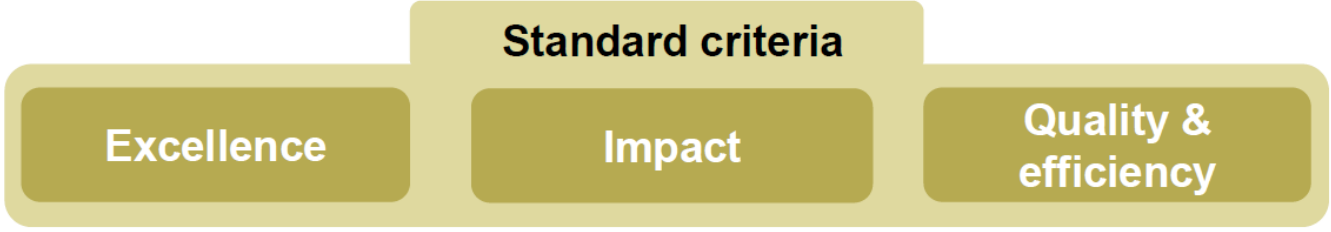
innovative medicines initiative

EFPIA: Los co-artífices de IMI

The IMI2 proposal life cycle
(for a 2-stages evaluation procedure)



Criterios de evaluación



- Two-stage evaluation: only **Excellence** and **Impact** considered at stage 1
- Thresholds and weighting in the **Call documents**
- Minimum of **3 independent experts** (possibility of 2 in a two-stage process)

NEW Each proposal **evaluated 'as it is'**, not as 'what could be'

Topics propuestos para la 10ª convocatoria

- **Understanding hypoglycaemia**: the underlying mechanisms and addressing clinical determinants as well as consequences for people with diabetes by combining databases from clinical trials
- How **big data** could support better diagnosis and treatment outcomes for **prostate cancer**
  Note: topic forms part of the IMI **Big Data for Better Outcomes** (BD4BO) programme
- Improving the care of patients suffering from **acute or chronic pain**
  Note: this topic consists of three subtopics:
  - A : Using patient reported outcome measures to improve the management of acute and chronic pain (PROMs)
  - B : Improving the translatability of pharmacodynamic biomarkers in pain pathways of healthy subjects and preclinical species (BIOM)
  - C: Improving translation in chronic pelvic pain (PCC)
- Creation of a pan-European **paediatric clinical trials** network
- **Biomanufacturing 2020**: Development of innovative high throughput analytical tools and methods to characterize cell culture fluid during development and commercial cell culture processes
- Unlocking the **solute carrier gene-family** for effective new therapies
- Enhanced **patient voice** in medicines lifecycle - **feedback wanted (see below)**
- Precision medicines approaches in **autism spectrum disorders**

Feedback on the topic on the patient voice in the medicines lifecycle

- IMI is keen to gather **wider stakeholder feedback** from all interested parties on the **patient voice topic**. If you have comments, please send them by e-mail to IMI at **consultations[AT]imi.europa.eu** by **Wednesday 21 September**. Comments received will be reviewed by staff from IMI, and shared with EFPIA representatives involved in the topic. Individual comments and details of contributors will not be made public. However, a **summary of the feedback received** will be **published** online.

All information regarding future IMI Call topics is indicative and subject to change. Final information about future IMI Calls will be communicated after approval by the IMI Governing Board.

La Iniciativa de Medicamentos Innovadores 2 – IMI2

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Apertura posible:19 octubre 2016 **(!?)**

Cierre posible: 24 enero 2017 (1ª fase; 17:00:00 CET) **(???)**

Vision general del proyecto

- To create a large collaborative paediatric network that will facilitate the development and availability of new drugs and other therapies, and the expansion of knowledge about drugs currently in practice for the entire paediatric population.

- This will be accomplished by not only advising on how best to do the necessary research, but by actually building sufficient infrastructure and best practices to support planning, conduct, and completion of all types of clinical studies (phase 1-4) by all kinds of sponsors (industry and non-industry) that can be used for regulatory review and approval; and for answering important scientific questions for already available drugs.

Funciones esperadas de la red

- "National hub coordinating centres" in each participating member state.
- Multiple clinical sites within each participating member state, including at least one "model site" per member state (which may double as the National hub coordinating centre).
- When fully functional, model sites should be able to provide well-trained clinical research nurses, data entry personnel, research pharmacy support, country-wide regulatory intelligence, program management and administrative support, and a physician trial coordinator.

To keep in mind: Suggested architecture of the **full** proposal

- The outlined architecture outlined for the full proposal is a suggestion. Different innovative project designs are welcome, if properly justified.
- The consortium is expected to have a strategy on the translation of the relevant project outputs into regulatory practices, and clinical and healthcare practice. A plan for interactions with Regulatory Agencies/health technology assessment bodies, with relevant milestones and resources allocated, should be proposed to ensure this.
- A plan for aspects related to sustainability, facilitating continuation of the network beyond the duration of the project should also be proposed (suggested Work Package 3).

Key deliverables (I)

- Establish the structure and governance of the network
- Set up and maintain groups of scientific experts to trigger innovation (develop and implement innovative methods, including dose selection, biomarkers, endpoints and/or study designs)
- Implement standing disease or condition-focused network clinical advisory groups
- Develop and implement standardised processes, procedures, and performance metricsTest the readiness of the network by conducting up to four industry-sponsored “proof of viability studies” selected by the industry consortium, and at least one non-industry sponsored study (phase I – IV) within the indicated duration of the IMI2 project.

Key deliverables (II)

- Build and expand the clinical trials infrastructure of the network at national hub sites and affiliated sites in multiple EU member states over the course of the IMI2 project.
- Develop a business model and funding mechanism that will provide sustainability of the network after the period of IMI2 funding.
- Build a process to open the network for submission of studies from all kinds of sponsors to increase the throughput of studies during the six year timeframe of the IMI2 project.
- Sustainability of the IMI paediatric network beyond the funding period of IMI2 is a key goal, and a sustainable successor organization to an IMI-2 funded European Paediatric Clinical Trials Network will be a key deliverable.

Suggested Work Packages

- **WP1: Project Management and Oversight of IMI project**
- **WP2: Organisation and Governance of the pan European Paediatric Clinical Trials Network**
- **WP3: Business Plan Development, Expansion of the Network, and Sustainability of the Network Sources of Funding post IMI2 support**
- **WP4: Scientific Advice, Feasibility and Innovation**
- **WP 5: Data Coordinating Centre and Data Quality Standards**
- **WP 6: Network Research Personnel Education and Training**
- **WP 7: Planning and Execution of Clinical Trials**

Aportación del consorcio industrial

Industry contribution:

- Clinical operations;
- Contracting expertise;
- Feasibility assessment;
- Clinical Project Management;
- Regulatory;
- Clinical Compliance;
- Legal;
- Up to four industry sponsored studies to proof viability of the network

Aportación del consorcio académico

- **Expected Applicant consortium contribution:**
  - Clinical operations;
  - Feasibility assessment;
  - Clinical Project Management;
  - Regulatory expertise with focus on clinical trial applications/ Investigational *Medicinal Product Dossier* (CTA/IMPD) application process;
  - Clinical Compliance, ICH GCP expertise;
  - Legal.

Aspectos a tener en cuenta en la preparación

- Six-year Project
- Design the project concept based on synergies with existing consortia (ECRIN a.o.)
- EMA will participate in some aspects of the creation of the network (it will join the ranked proposal at phase 1). The EMA will carry its own cost.

http://www.imi.europa.eu/

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