MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de
medicamentos y
productos sanitarios



# Role of the EU Innovation Network & current experiences from an existing national Innovation Office

César Hernández García
Head of Department of Medicines for Human Use
Spanish Agency of Medicines and Medical Devices

# the origins of the Spanish Innovation Office...

O.J.D.: 300830
E.G.M.: 1443000

EL MUNDO
DEL SIGLO VEINTIUNO

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Páginas: 34

**BIOMEDICINA** / El proyecto de Bernat Soria, aprobado ayer, pretende acercar las últimas investigaciones a los enfermos / El cáncer tendrá un plan propio para nuevas terapias

# Sanidad impulsa ensayos clínicos con células madre para males incurables

# The Ministry of Health promotes clinical trials with stem cells for untreatable diseases

Red de Terapia Celular

Web de la Red de Terapia Celular

INICIO | OBJETIVOS | GRUPOS | LA TERAPIA CELULAR | NORMATIVA | NOTICIAS | ENLACES | BOLSA DE TRABAJO | CONTACTOS | NOVEDADES | FTP

Usuario: Contraseña : Acceder a la parte privada

- Grupo 1: *J. García-Sancho, A. Sánchez, A. San Román*
- Grupo 2: *J.J. Toledo, J. López Barneo, R. Pardal*
- Grupo 3: *Bernat Soria, Francisco Bedoya*
- Grupo 4: *Isabel Fariñas*
- Grupo 5: *Salvador Martínez, José María Moraleda*
- Grupo 6: *J. Alberch, J. Canals*
- Grupo 7: *Lina Badimón, Jerónimo Blanco*
- Grupo 8: *Antonio Bernad, Damián G. Olmo*
- Grupo 9: *Miguel Torres*
- Grupo 10: *Agustín Zapata*
- Grupo 11: *José Carlos Segovia*
- Grupo 12: *Alberto Martínez Serrano*
- Grupo 13: *Josße Becerra Ratia*
- Grupo 14: *Felipe Prósper*
- Grupo 15: *C. del Cañizo, J. San Miguel*
- Grupo 16: *José Luis Labandeira García*
- Grupo 17:

**Introducción :**

Esta red multidisciplinaria consta de 19 grupos de gran tradición en Fisiología Celular Básica, Desarrollo, y Genética cuyos investigadores han comprendido la necesidad de establecer contactos grupos clínicos cercanos para abordar los problemas científicos, terapéuticos y organizativos que hagan posible en el futuro la aplicación y gestión de estas nuevas terapias dentro de nuestro sistema sanitario público.

El número componentes de la Red TERCEL podría incrementarse con nuevos grupos emergentes sin otro requisito que la calidad científica y la aplicabilidad al sistema de salud.

***Experiencia del Experiencia de los grupos integrantes de la red***

La red de terapia celular surge desde unos planteamientos de investigación básica puestos al servicio de la mas alta tecnología sanitaria. Para ello el catalizador ha sido la necesidad de poner al servicio de las distintas redes temáticas de enfermedades de alta prevalencia el interés y la ilusión por esta nueva terapia de un grupo de científicos básicos que desde la Fisiología celular (Grupos 1,2,3), la Embriología y el Desarrollo (grupos3, 5) la Biología Molecular (grupos 4,6) y la investigación vascular grupo (7) han desarrollado.

Estos científicos han brindado su larga experiencia en el estudio de la caracterización morfofuncional células aisladas a la puesta en marcha de diseños de aplicación clínica con sus colegas médicos mas cercanos.

En este sentido fue pionero **el grupo 2, que dirige el Dr. López Barneo en Sevilla** . Este grupo inició en los años 80 los estudios de "Patch Clamp" en España y mas tarde los aplicó a la fisiología de células quimiorreceptoras aisladas del seno carotídeo. Con este bagaje de indudable valor, inició sus ensayos de terapia celular de células procedentes de glomus carotídeo en animales hace cinco años y desde hace dos realiza autotransplantes de células dopaminérgicas procedentes del glomus en pacientes de Parkinson. Estas células son disociadas agudamente y transplantadas a la substancia nigra del paciente. El ensayo piloto de factibilidad y seguridad, desarrollado en el **Hospital Virgen de las Nieves de Granada** , está en fase de análisis de resultados por NMR cuantitativa y su puesta en marcha puede ser un modelo para todos

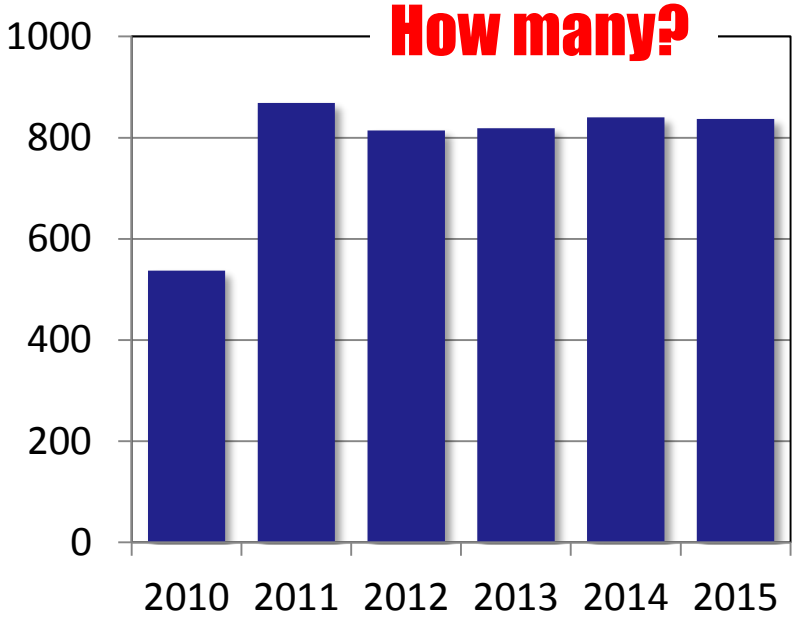
**More than 25 groups listed...**


**Objective 3**
**To support research, development and innovation**

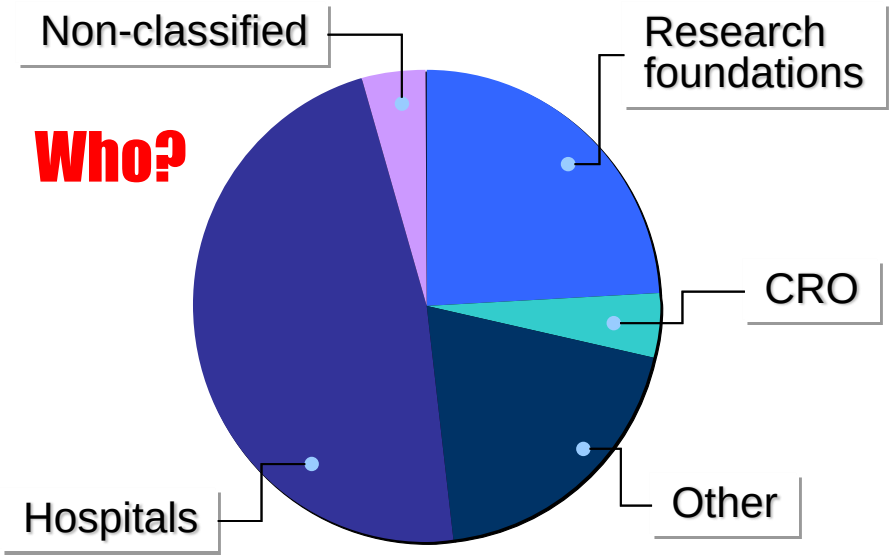
**Strategy 3.2.**
**To facilitate investigation with advanced therapies and non-commercial research**

**Project 3.2.1**
**To set up an Office for supporting clinical investigation**

## How many?

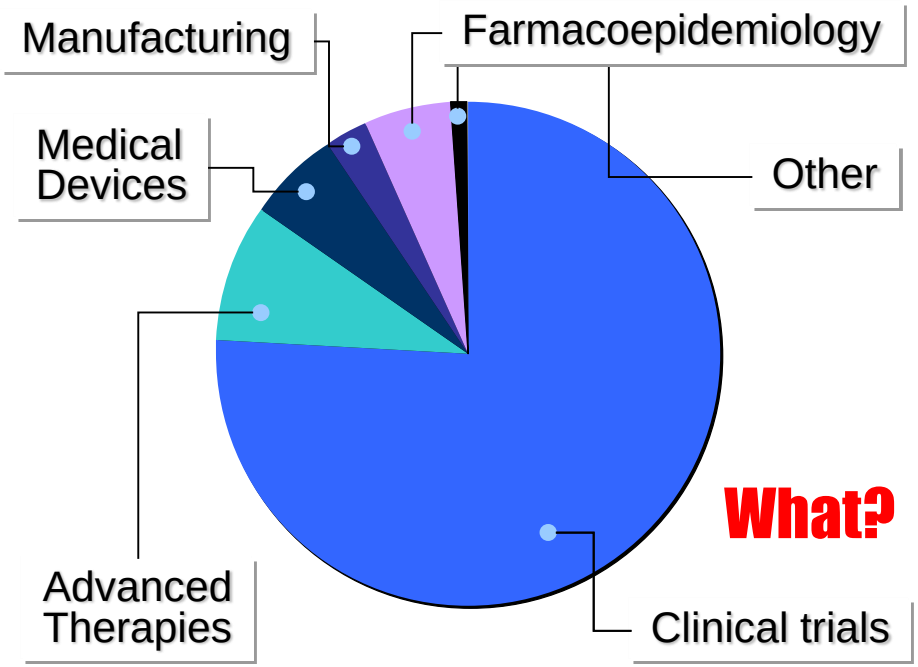


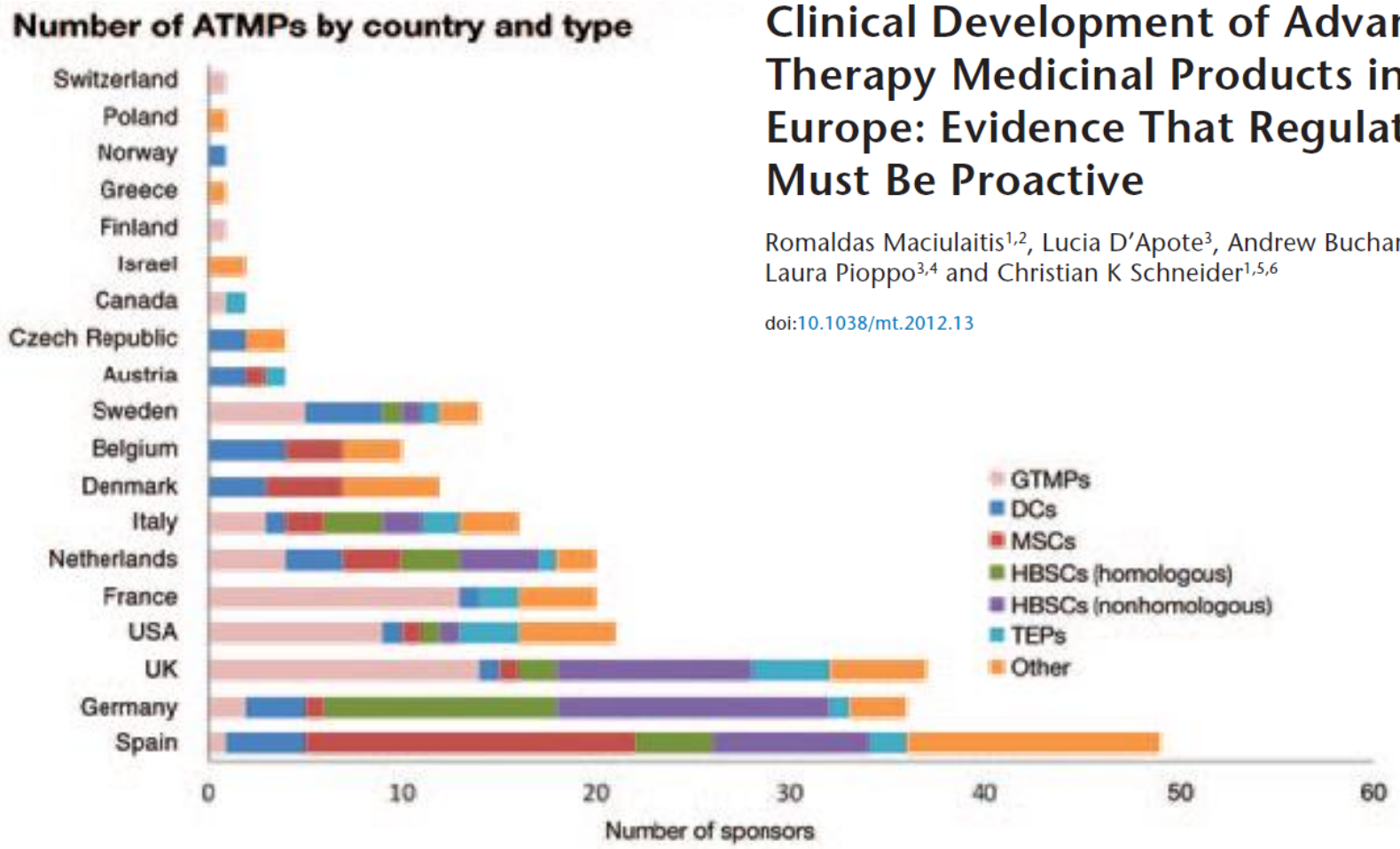

## Who?




## Where?

## What?



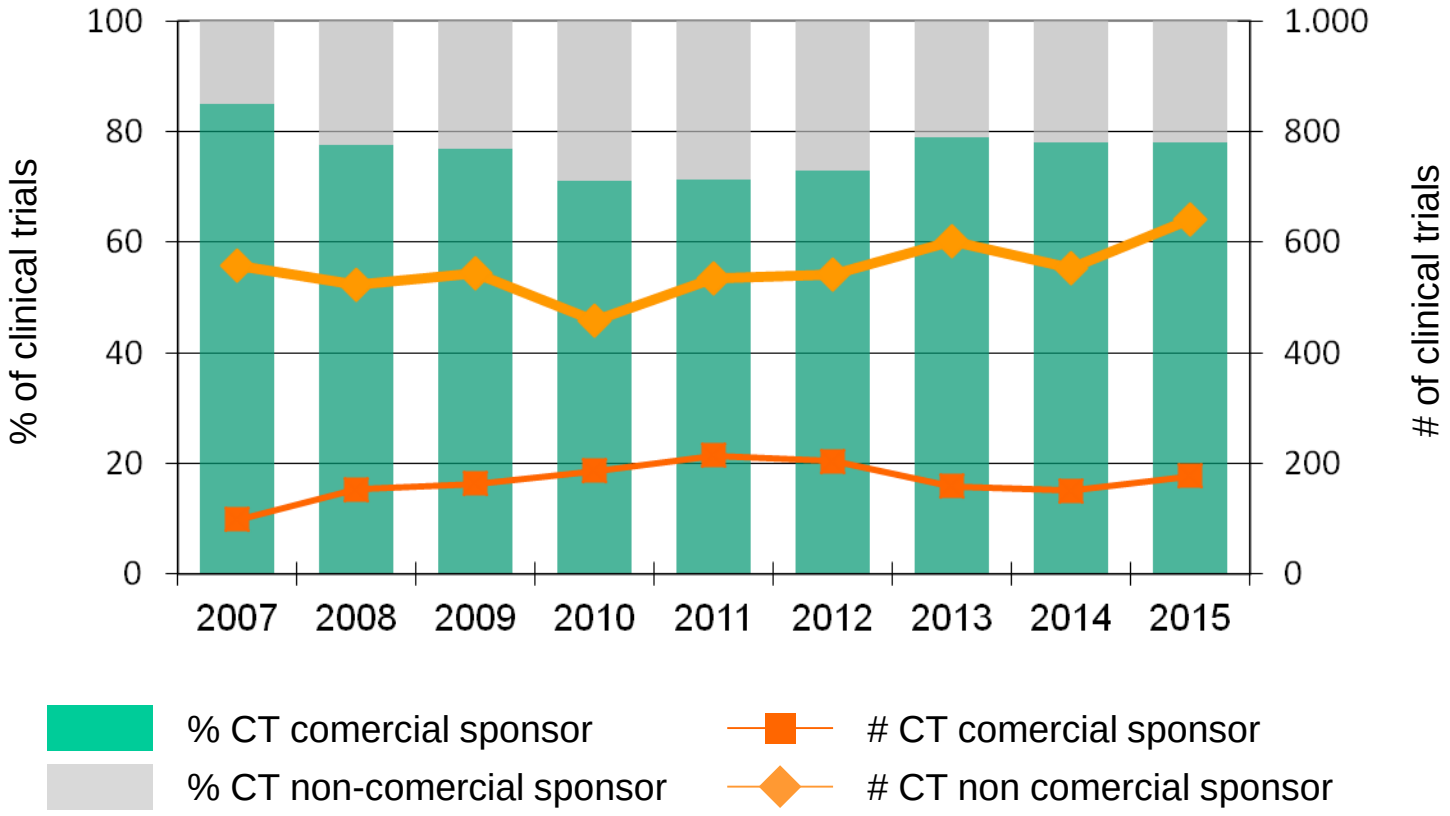



# Clinical Development of Advanced Therapy Medicinal Products in Europe: Evidence That Regulators Must Be Proactive

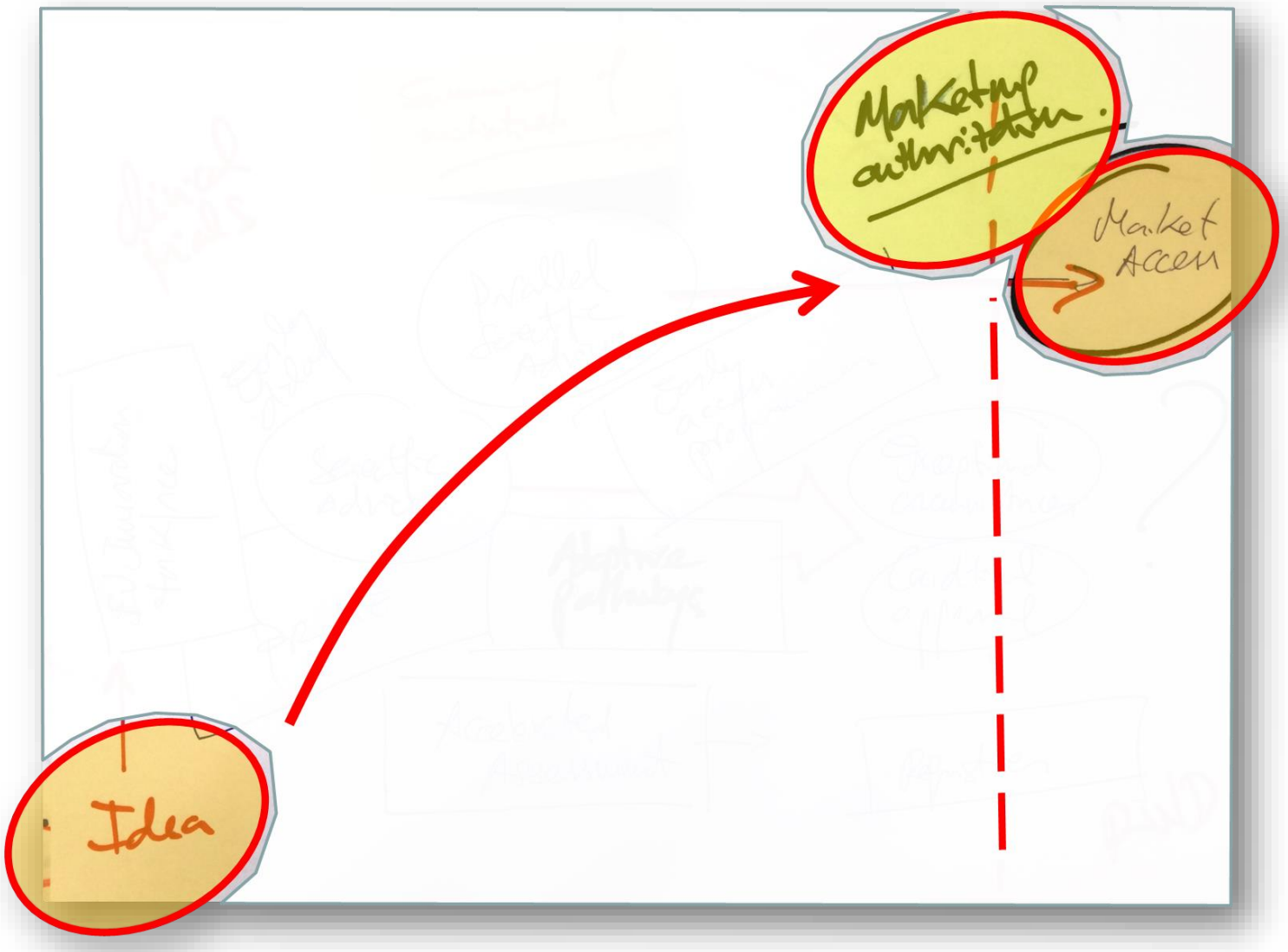
Romaldas Maciulaitis[1,2], Lucia D'Apote[3], Andrew Buchanan[3], Laura Pioppo[3,4] and Christian K Schneider[1,5,6]

doi:10.1038/mt.2012.13

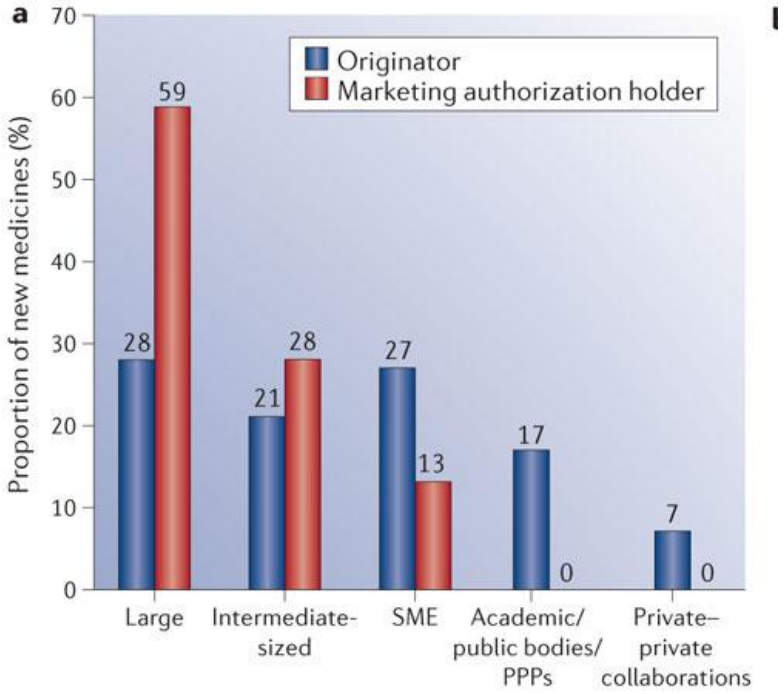
# Number and percentage of CT by sponsor



# the (regulatory) EU landscape of innovation


Idea
Market Access

# Origin of new medicines in the EU (2010-2012)




Of 94 novel medicinal products authorised

- Large majority marketed by large or intermediate sized companies
- SMEs and academia at the origin of innovation

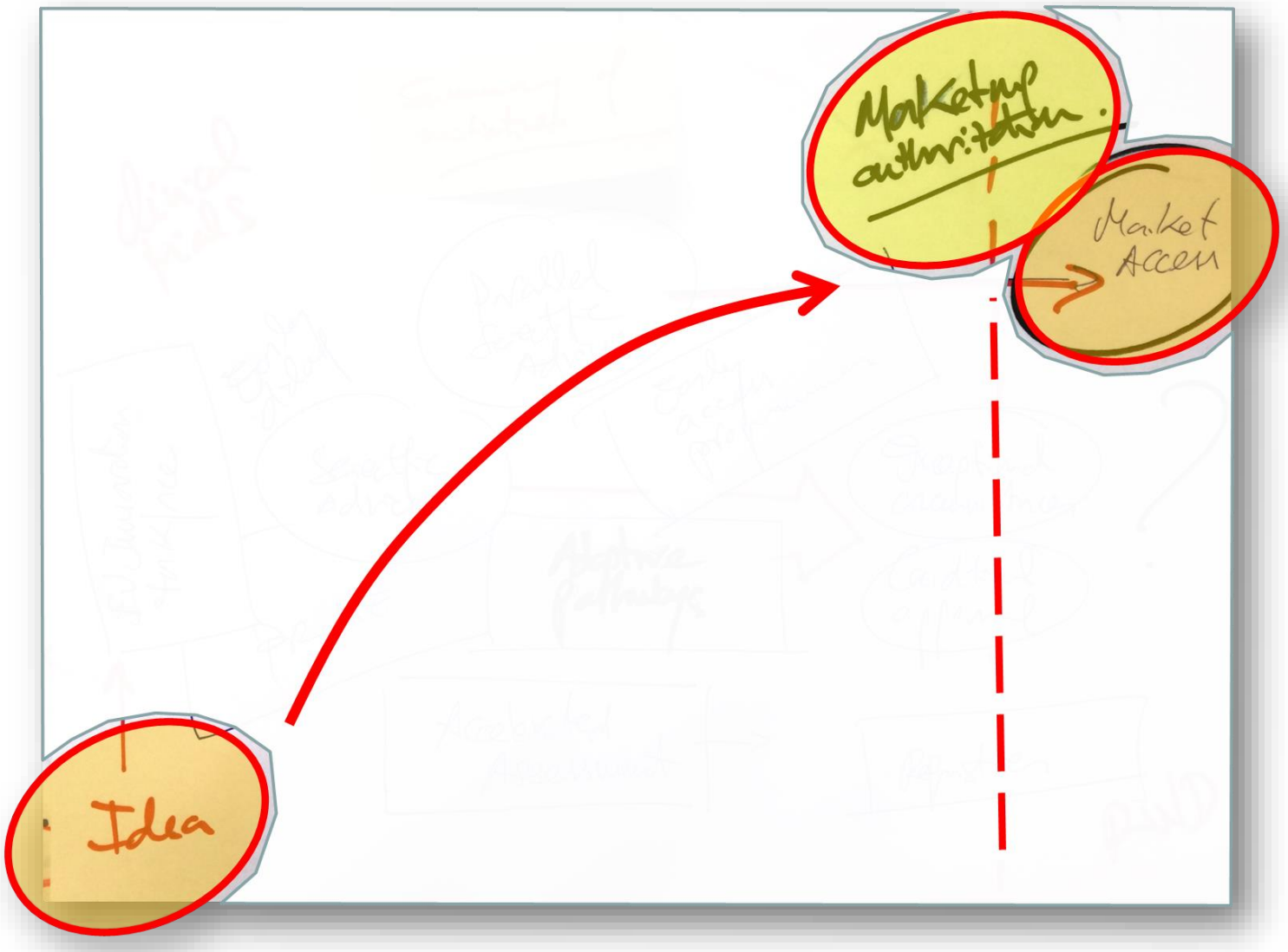
H. Lincker et al; Nature Reviews Drug Discovery Vol: 13, pp. 92–93 (2014)

# Why do medicine development programs fail (or get delayed)?

- When further development proves initial hypotheses wrong (often inevitable)
- Inappropriate development program, wrong studies (usually preventable)

Who takes the risk?
Companies, investors, and
patients engaged in clinical trials

From Guido Rasi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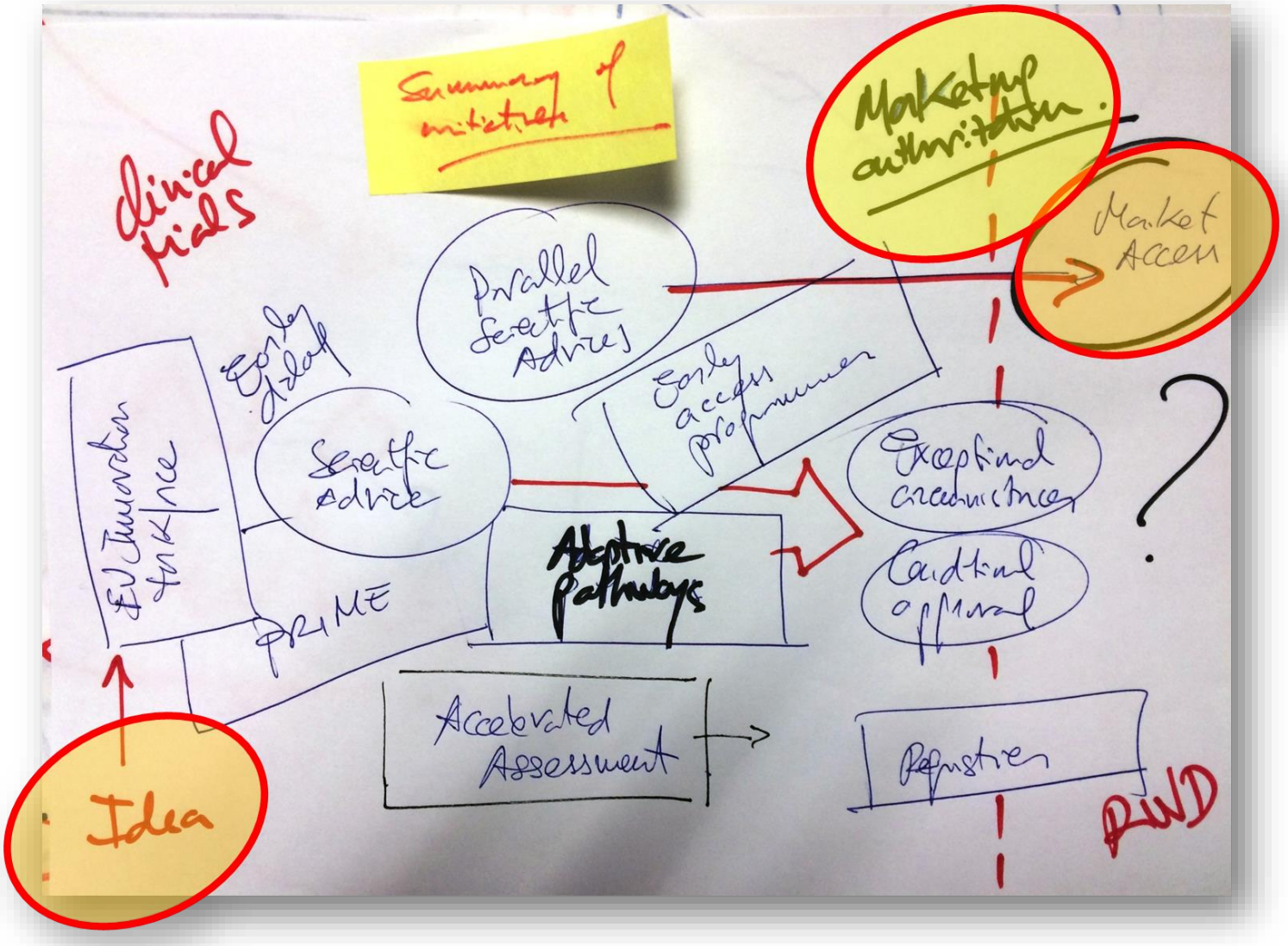
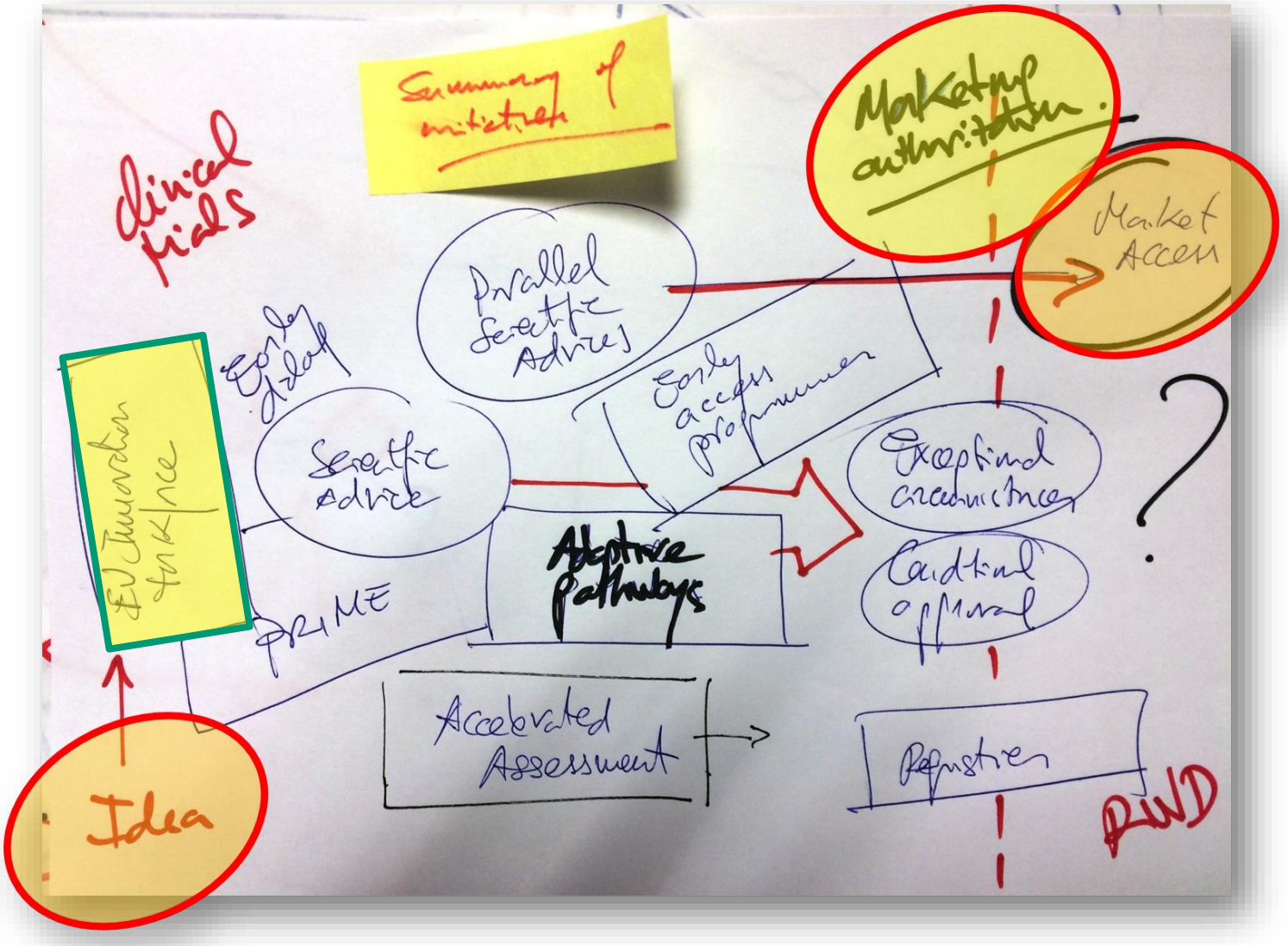
Market Access


Summary of initiatives
Marketing authorisation
Market Access
Clinical trials
Parallel Scientific Advice
Early dialogue
Scientific advice
Early access programmes
EU Innovation Network
PRIME
Adaptive Pathways
Exceptional circumstances
Conditional approval
Accelerated Assessment
Registration
Idea
R&D
?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# European Innovation Network

- Since 2011, the EMA ITF and innovation offices of some NCAs have had teleconferences on a regular basis

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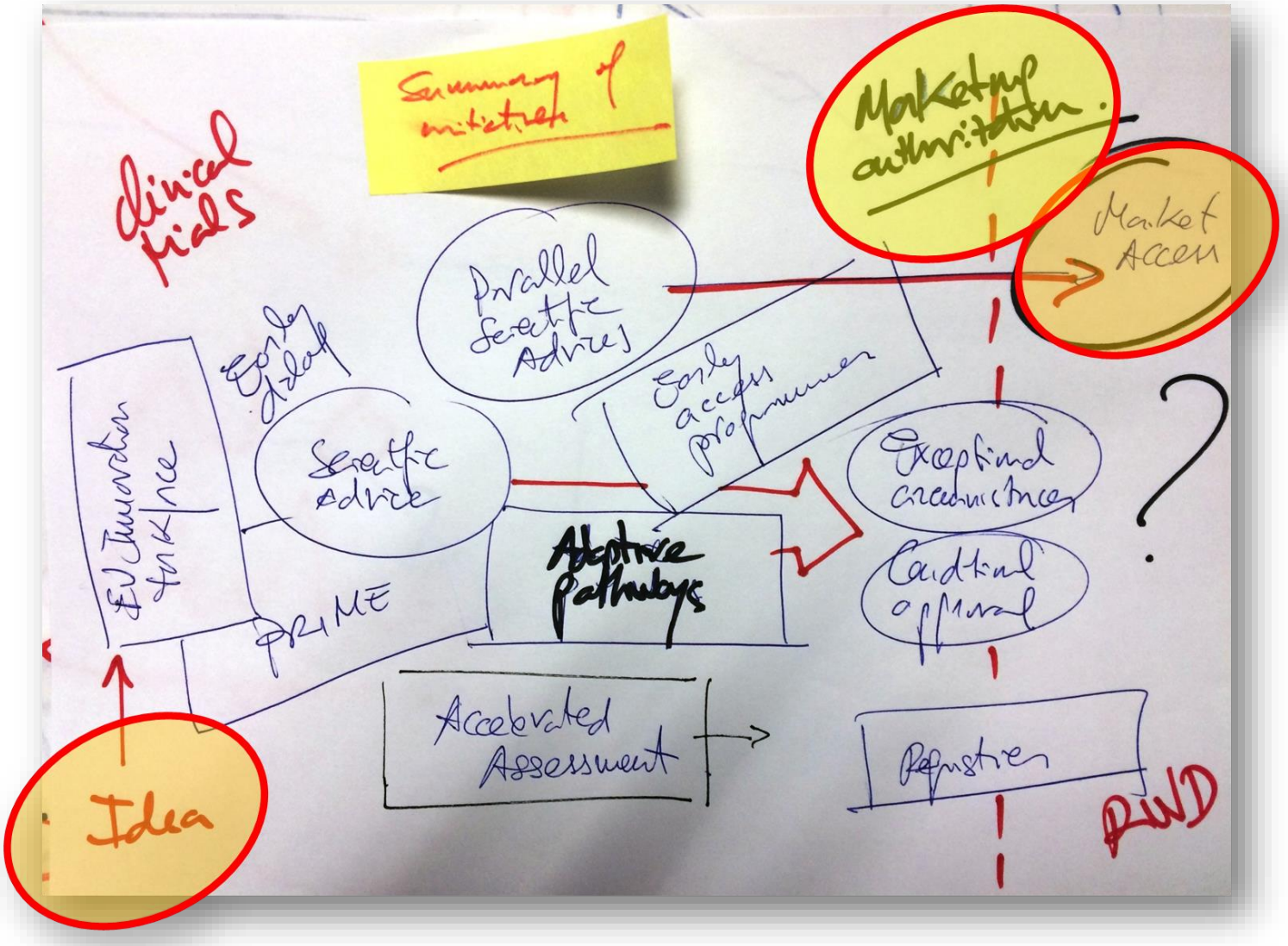
- Since 2011, the EMA ITF and innovation offices of some NCAs have had teleconferences on a regular basis
- The EU Medicines Agencies Network Strategy to 2020 recognised the important role of the EMA ITF and national innovation offices
- The HMA Multi-Annual Workplan (MAWP) support a coordinated and integrated view of NCAs' innovation offices and EMA's Innovation Task Force

# What is changing in the innovation offices?

- **Recruitment** of new members
  →Talk to your colleagues
- **Evolution of an innovation office**
  contact person → participation in the EU-IN work → connections to internal stakeholders → establishment of an innovation office → integration to local innovation support system internally and locally
- **Evolution of the EU-IN**
  Consolidation of the network: common core/special functions → systematic collection of data → generation of aggregated data → reporting to HMA and EMA → establishment of EU-IN as an integrated part of the regulatory support system → networking with non-regulatory bodies at the EU level

# the (new) Spanish Innovation Office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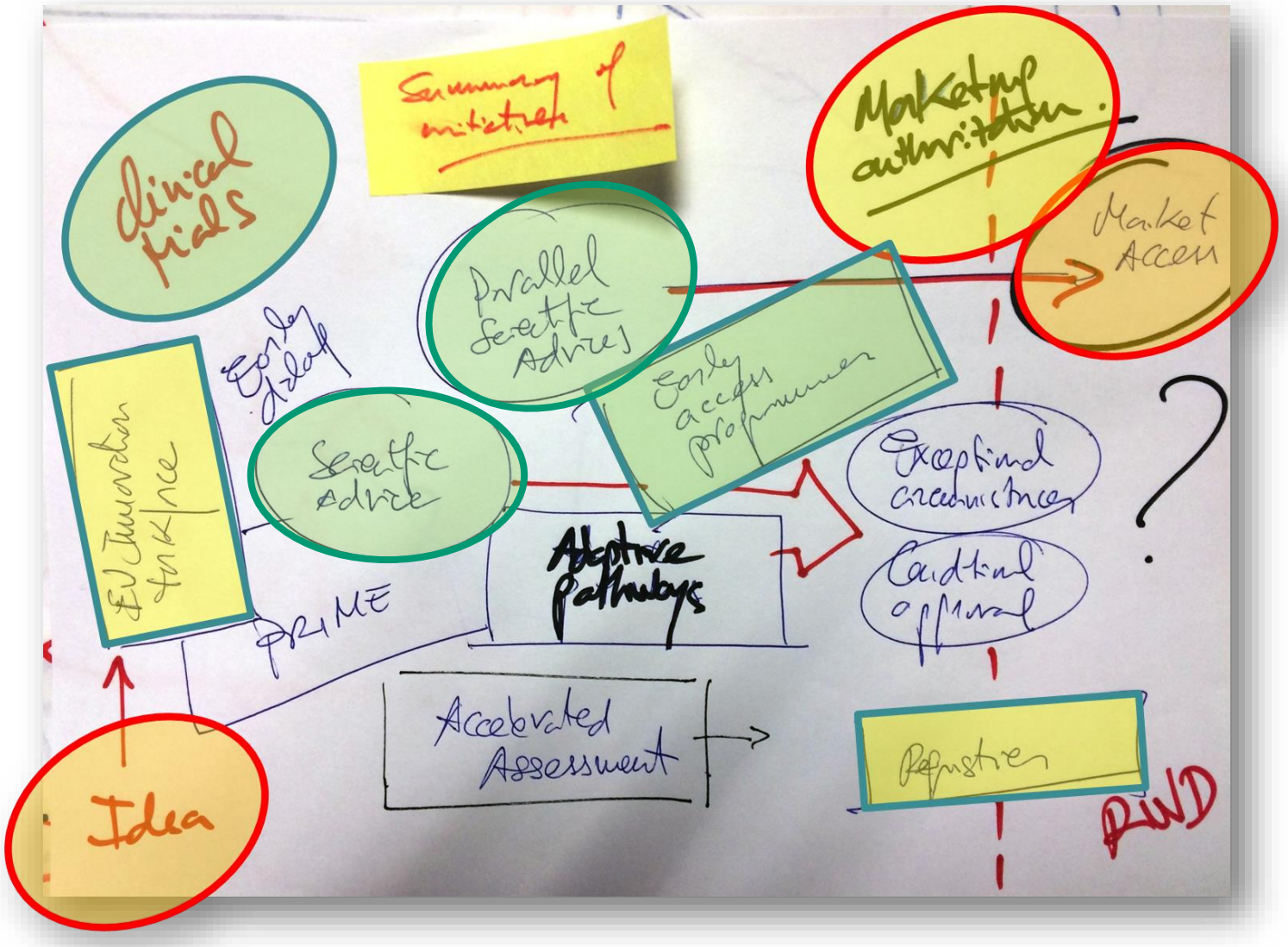
PRIME
Accelerated Assessment
Idea
Registration
R&D


Clinical trials
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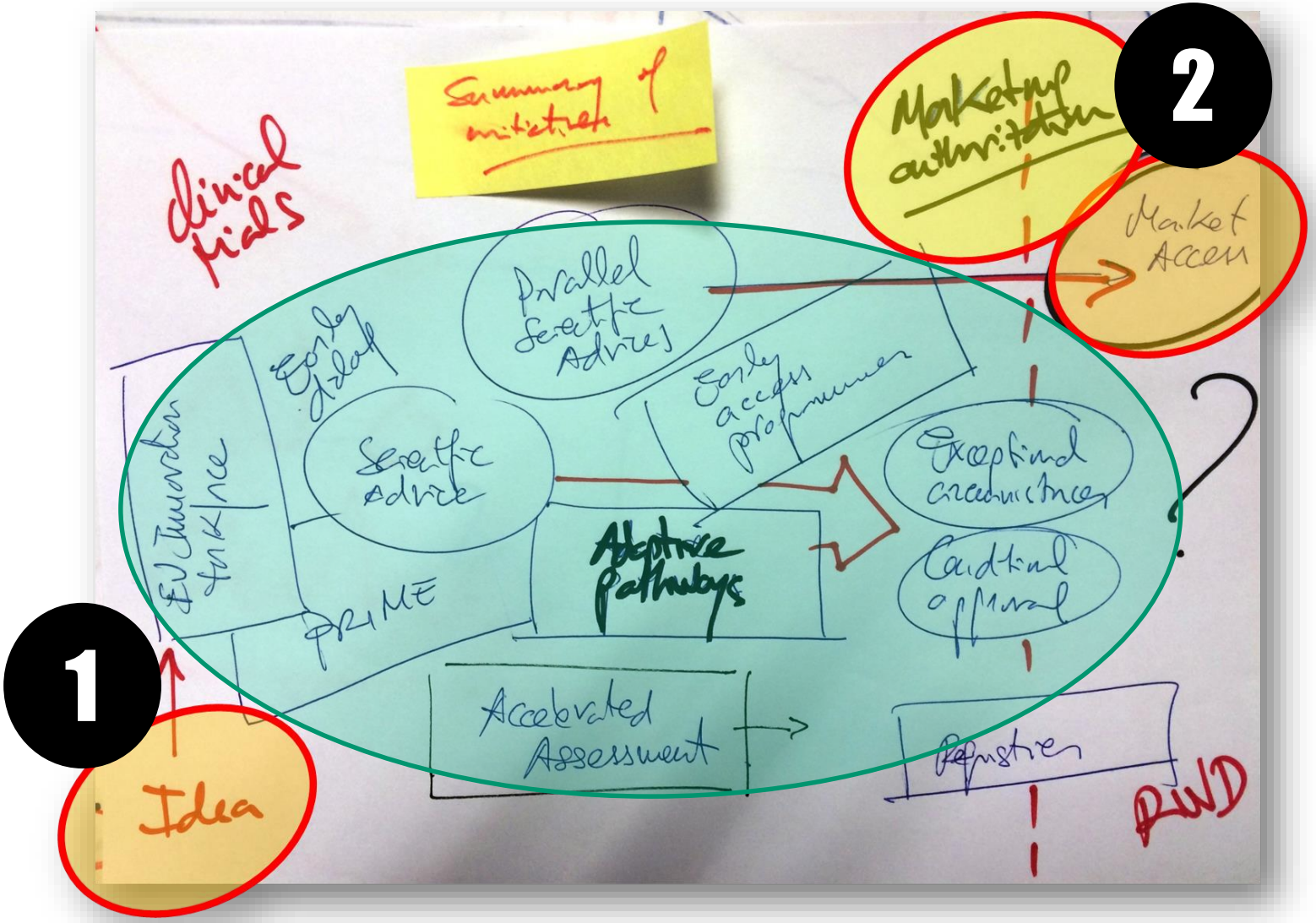
PRIME
Adaptive Pathways
Exceptional circumstances
Conditional approval
?
Accelerated Assessment
Registries
Idea
R&D




# Take off and landing

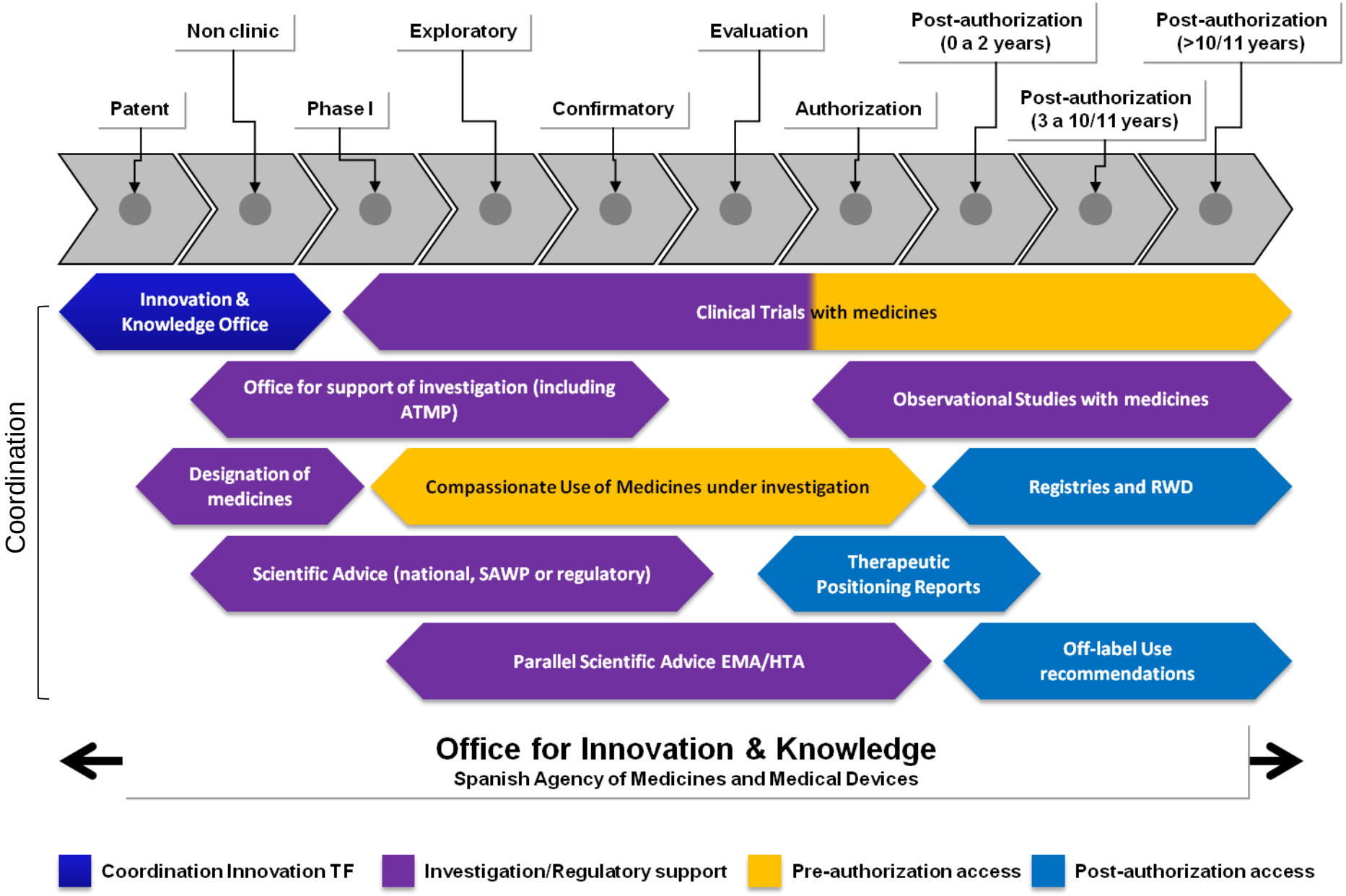
# 1 Office for Innovation & Knowledge
# Integrating activities...

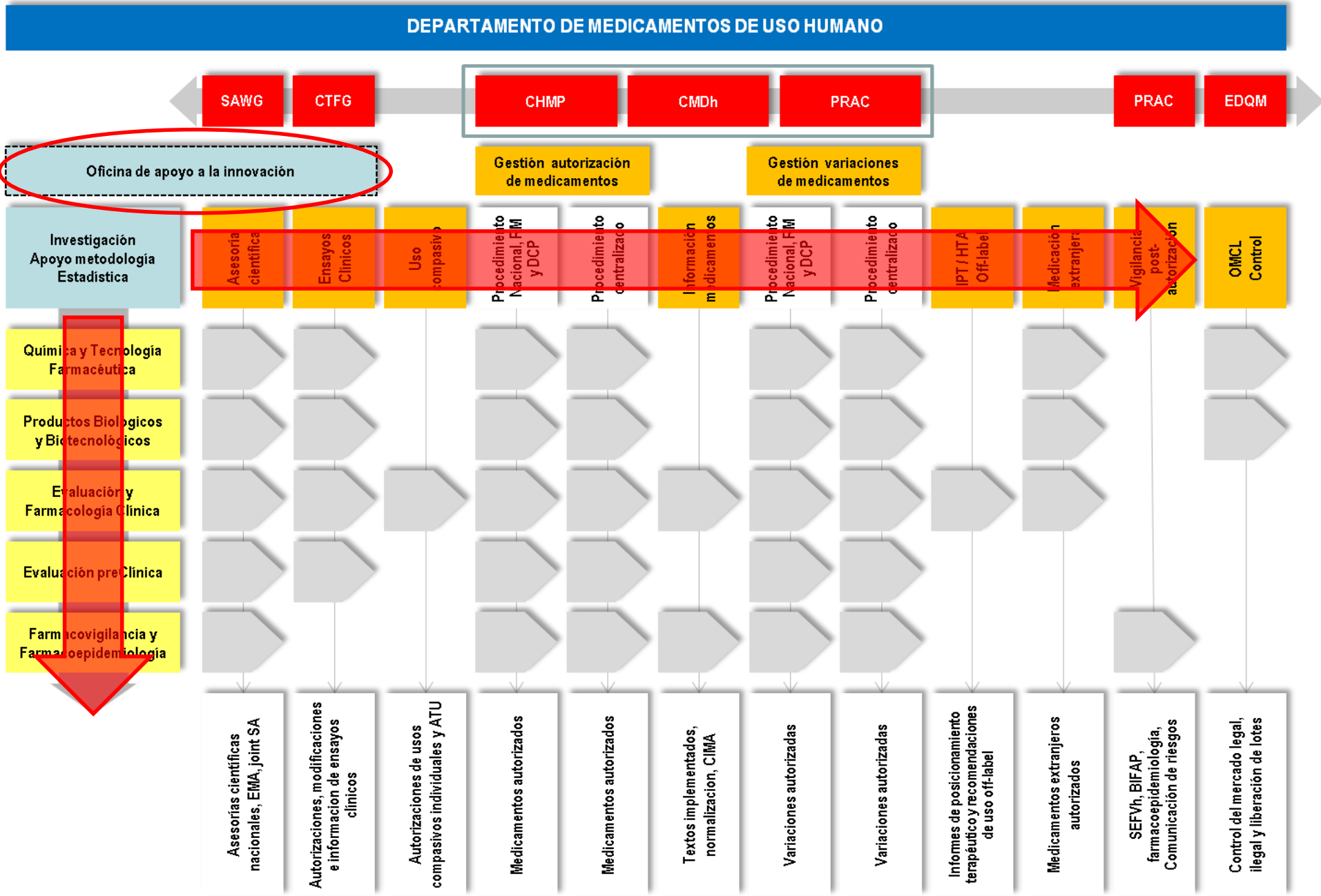
# Office for support of INNOVATION and KNOWLEDGE of medicinal products

–

Spanish Agency
of Medicines
and Medical Devices


Integration in the EU
Support for investigation
OFFICE FOR SUPPORT OF INNOVATION AND KNOWLEDGE OF MEDICINAL PRODUCTS
Post-authorisation access
Pre-authorisation access


Patent
Non clinic
Phase I
Exploratory
Confirmatory
Evaluation
Authorization
Post-authorization (0 a 2 years)
Post-authorization (3 a 10/11 years)
Post-authorization (>10/11 years)
Innovation & Knowledge Office
Clinical Trials with medicines
Office for support of investigation (including ATMP)
Observational Studies with medicines
Designation of medicines
Compassionate Use of Medicines under investigation
Registries and RWD
Scientific Advice (national, SAWP or regulatory)
Therapeutic Positioning Reports
Parallel Scientific Advice EMA/HTA
Off-label Use recommendations
Coordination
Office for Innovation & Knowledge
Spanish Agency of Medicines and Medical Devices
Coordination Innovation TF
Investigation/Regulatory support
Pre-authorization access
Post-authorization access


DEPARTAMENTO DE MEDICAMENTOS DE USO HUMANO
SAWG
CTFG
CHMP
CMDh
PRAC
PRAC
EDQM
Oficina de apoyo a la innovación
Gestión autorización de medicamentos
Gestión variaciones de medicamentos
Investigación
Apoyo metodología
Estadística
Asesoría científica
Ensayos Clínicos
Uso compasivo
Procedimiento Nacional, RM y DCP
Procedimiento centralizado
Información medicamentos
Procedimiento Nacional, RM y DCP
Procedimiento centralizado
IPT / HTA Off-label
Medicación extranjera
Vigilancia post-autorización
OMCL Control
Química y Tecnología Farmacéutica
Productos Biológicos y Biotecnológicos
Evaluación y Farmacología Clínica
Evaluación preClínica
Farmacovigilancia y Farmacoepidemiología
Asesorías científicas nacionales, EMA, joint SA
Autorizaciones, modificaciones e información de ensayos clínicos
Autorizaciones de usos compasivos individuales y ATU
Medicamentos autorizados
Medicamentos autorizados
Textos implementados, normalizacion, CIMA
Variaciones autorizadas
Variaciones autorizadas
Informes de posicionamiento terapéutico y recomendaciones de uso off-label
Medicamentos extranjeros autorizados
SEFVh, BIFAP, farmacoepidemiología, Comunicación de riesgos
Control del mercado legal, ilegal y liberación de lotes

## 1. Coordination with the European Innovation Offices Network.

### ADDRESSEES

Academic groups, independent investigators, cooperative groups, hospitals, research foundations, start-ups, small and medium-sized companies

### PRODUCTS

Any type of medicinal product in initial phases of development

### INTERACTION

Face-to-face meetings or individual teleconferences, simple consultations [2], collective sessions or courses

### EXPECTED RESULT

Identification of innovative projects, information on the regulatory tools available and appropiate for each specific project and integration in the European system for authorisation of medicinal products or other support tools at a national level.

### INFORMATION AND CONTACT POINT

INNOV@aemps.es

# 2.1. Independent Clinical Research Support Office

## ADDRESSEES

Academic groups, independent investigators, cooperative groups, hospitals, research foundations, start-ups

## PRODUCTS

Clinical trials to be conducted with any type of medicinal product

## INTERACTION

Face-to-face meetings or individual teleconferences, simple consultations [3]

## EXPECTED RESULT

Regulatory or scientific support in the process of application, authorisation or classification of a clinical trial

## INFORMATION AND CONTACT POINT

More information on the Office, procedure and application form available in the link: http://www.aemps.gob.es/investigacionClinica/medicamentos/oficinApoyo.htm

3. These are specific consultations that are able to be resolved in writing or during face-to-face meetings or teleconferences given that they do not reach the degree of complexity that makes a formal advice necessary.

# 2.2 Support for the development of Advanced Therapy Medicinal Products

## ADDRESSEES

Academic groups, independent investigators, cooperative groups, hospitals, research foundations, start-ups, small and medium-sized companies, pharmaceutical industry in general

## PRODUCTS

Investigational therapies in which there are doubts with regard to their classification as advanced therapy medicinal products

## INTERACTION

Simple consultations [4]

## EXPECTED RESULT

Identification and classification of innovative projects related to advanced therapies, regulatory and scientific support in these developments

## INFORMATION AND CONTACT POINT

Access to the telematic application form for advice in the following link:
**http://www.aemps.gob.es/investigacionClinica/medicamentos/form_solicitudAsesora_terapiAvanzada.htm**

# 2.3 National scientific advice

## ADDRESSEES

Academic groups*, independent investigators*, cooperative groups*, hospitals*, research foundations*, start-ups, small and medium-sized companies, pharmaceutical industry in general

## PRODUCTS

Any type of medicinal product for which an application for marketing authorisation is being considered or an application for conducting observational studies aimed at improving knowledge of the medicinal product

## INTERACTION

Formal scientific advice

## EXPECTED RESULT

Scientific support of the Health Authorities in the investigation of medicinal products in their different phases of development

## INFORMATION AND CONTACT POINT

More information on the procedure of scientific advice is available in the following link: **http://www.aemps.gob.es/industria/regMedicamentos/asesoriasCientificas/home.htm**

* Scientific advice for investigators in the academic field, hospital units or non commercial bodies does not entail payment of fees

# 2.4 Scientific Advice in the EMA Scientific Advice Working Party (European advice)

## ADDRESSEESS

Academic groups, independent investigators, cooperative groups, hospitals, research foundations, start-ups, small and medium-sized companies, pharmaceutical industry in general

## PRODUCTS

Any type of medicinal product

## INTERACTION

Formal scientific advice in the EMA

## EXPECTED RESULT

Scientific support of the European Health Authorities in any aspect related to the development of the medicinal product or its conditions of authorisation

## INFORMATION AND CONTACT POINT

Additional information on the activity and procedures of the European scientific advice working group can be found in the following link: **http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/CHMP/people_listing_000022.jsp**

# 2.5 Regulatory advice

## ADDRESSEES

Academic groups*, independent investigators*, cooperative groups*, hospitals*, research foundations*, start-ups, small and medium-sized companies, pharmaceutical industry in general

## PRODUCTS

Any type of medicinal product for which an application for marketing authorisation or a change in the conditions of authorisation is being considered

## INTERACTION

Formal regulatory advice

## EXPECTED RESULT

Regulatory support of the Health Authorities in the investigation of medicinal products in their different phases of development. Resolution of consultations regarding the application of current legislation and regulatory strategy

## INFORMATION AND CONTACT POINT

More information on the procedure of scientific advice is available in the following link: **http://www.aemps.gob.es/industria/regMedicamentos/asesoriasCientificas/home.htm**

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# 2.6 Parallel scientific advice with HTA

## ADDRESSEES

Academic groups*, independent investigators*, cooperative groups*, hospitals*, research foundations*, start-ups, small and medium-sized companies, pharmaceutical industry in general

## PRODUCTS

Any medicinal product that can benefit from early interaction with HTA

## INTERACTION

Formal advice on aspects regarding the assessment of health technologies

## EXPECTED RESULT

Optimisation of the development of medicinal products as a result of the early incorporation of aspects and considerations related to the subsequent assessment of health technologies

## INFORMATION AND CONTACT POINT

SA_HTA@aemps.es

* La asesoría científica a investigadores del ámbito académico, unidades hospitalarias o entidades sin ánimo de lucro no conlleva el pago de tasas

# Summary

- Integrated view along the entire life cycle of medicines from the idea to the access
- Integrated within the European Innovation Network
- A dedicated contact point in every moment of development for a given product with a shared and common vision
- More information: https://www.aemps.gob.es/en/medicamentosUsoHumano/ofi-innova-conocimiento-med/home.htm

Thank you