Hands-on the Regulations in Colombia

Main regulations & features

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Agenda

- **Regulatory Framework: 1990/2000**
  - 1990/2000… up to date
- **Resolution 2378, Turning Point:**
  - Sites changes
  - Protocol evaluation
  - Safety Reports
- **Local Special Requirements**
  - Inform Consent Process
  - IP Labelling
  - Deviation Reports
  - Contracts
  - Placebo
  - Extension treatment
  - INVIMA FU visits
  - Ethics Committee

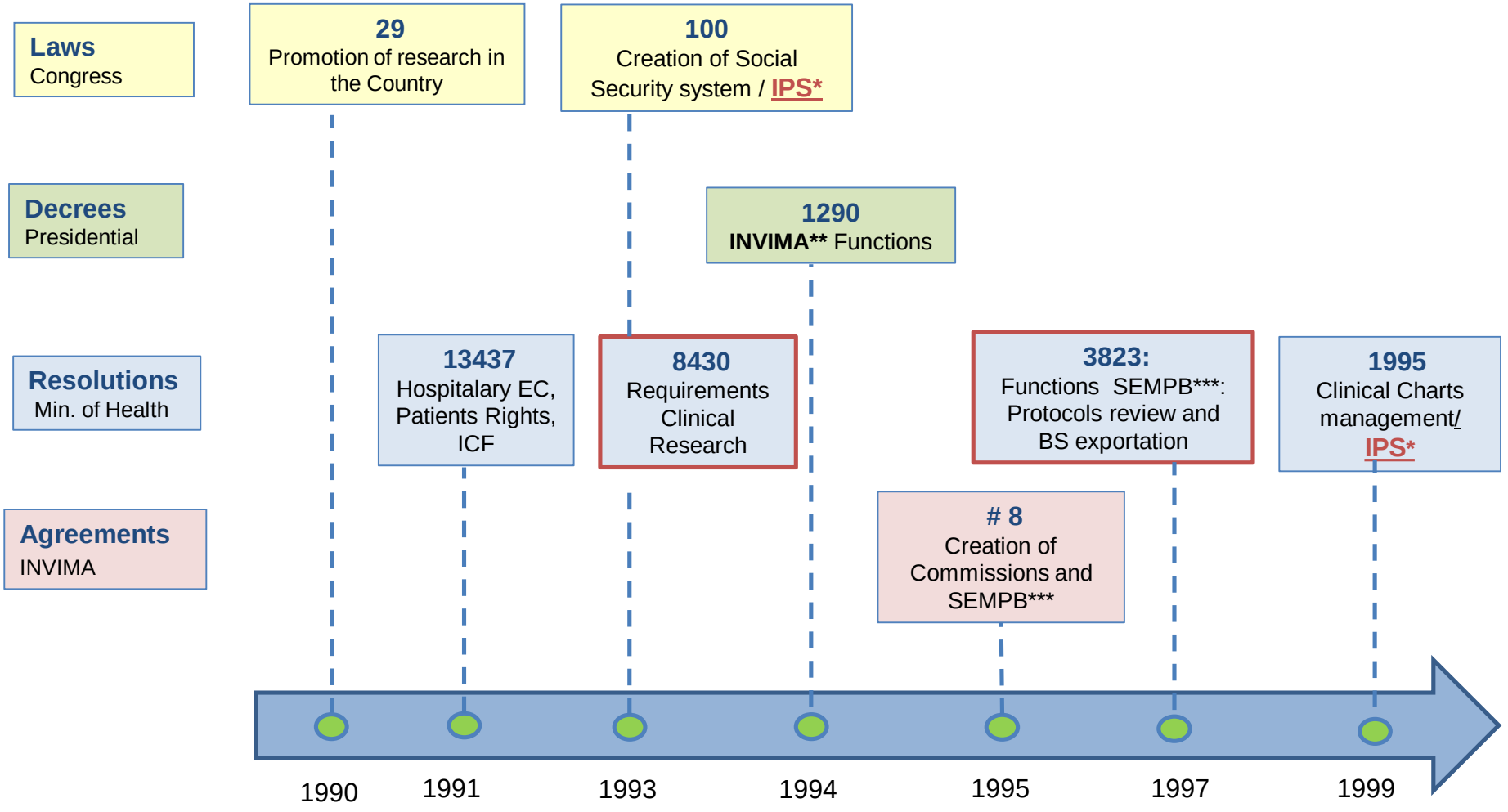
Agenda

- **Other Requirements**
- **What we have to date**
- **Regulatory timelines and Pathway**
- **Conlcusions**
  - Advantages
  - Oportunities
- **Resources**

Regulatory Framework Clinical Research

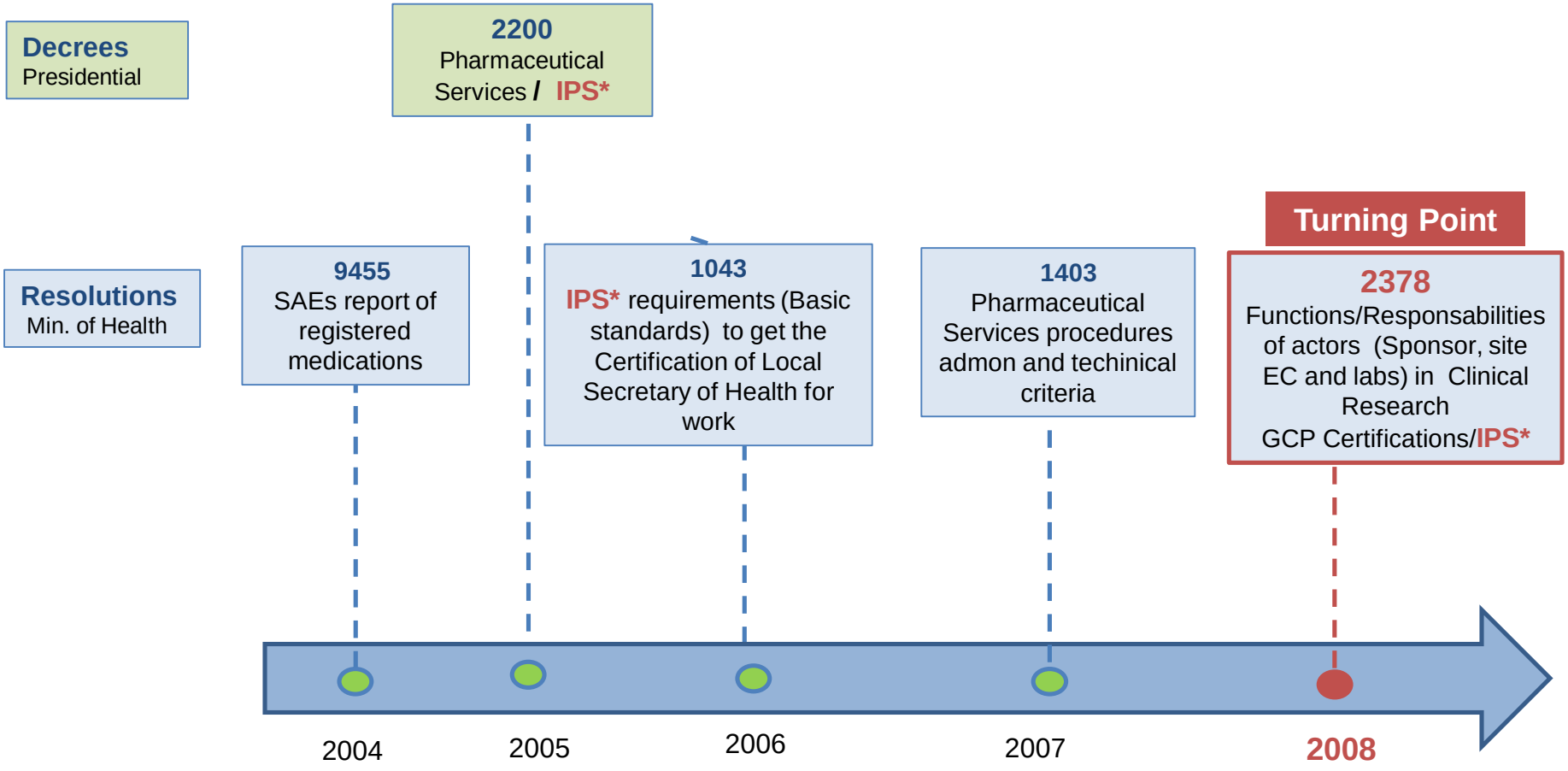
1990- up to date

Regulatory Framework 1990



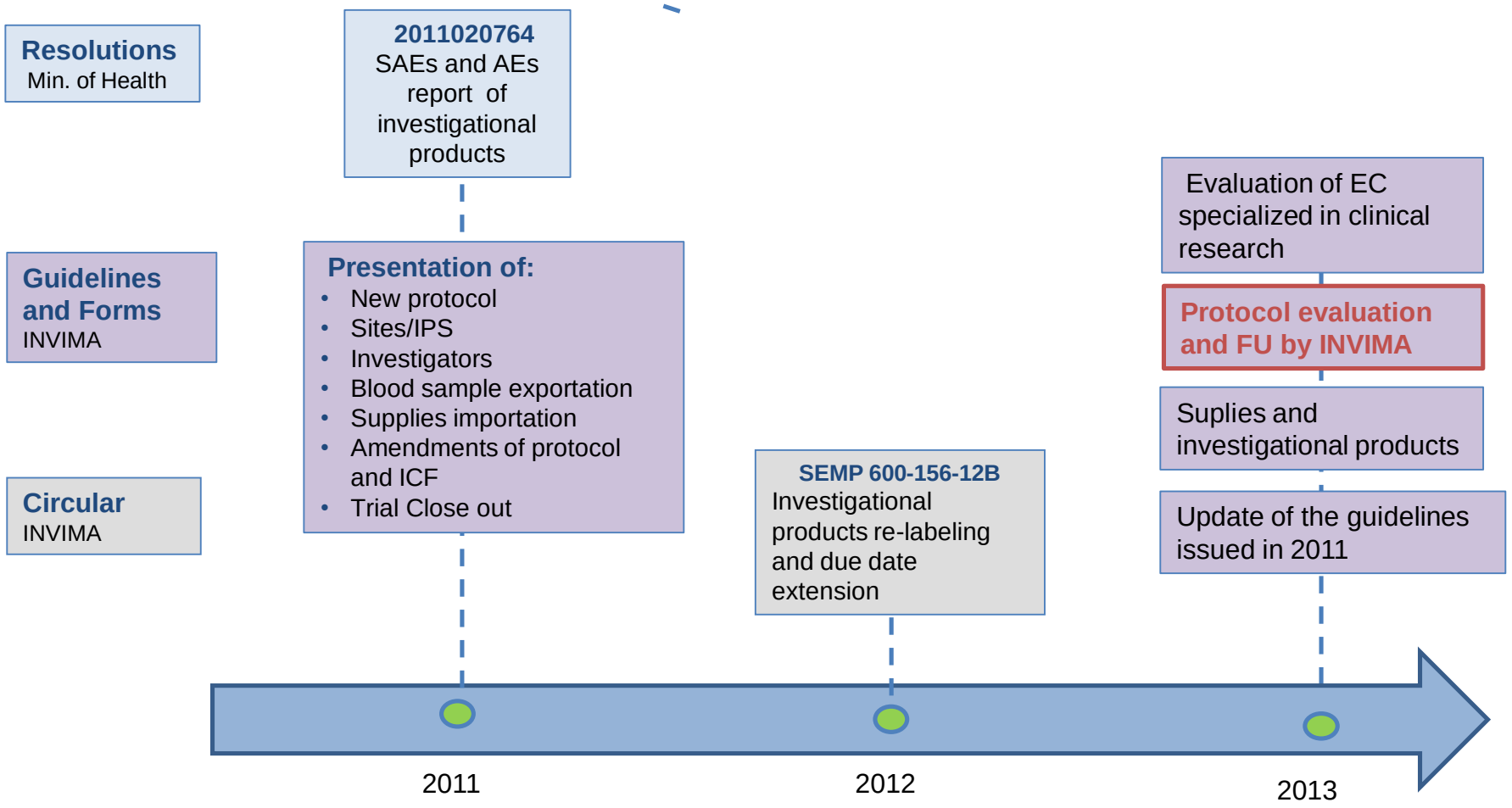
*** IPS:** Service Health Institution
****INVIMA**: National Institute for Drugs and Food Vigilance
***SEMPB : Specialized Board of Drugs and Biological ¨Products

Regulatory Framework 2000



*** IPS:** Service Health Institution

Regulatory Framework 2011…..Up to date



*** IPS:** Service Health Institution

Res. 2378

TURNING POINT

2008

Resolution 2378, Turning Point

- ✓ Sites: IPS and certified services
- ✓ Site staff : Health care professionals (nurses, doctors, pharmaceutical chemist and bacteriologist)
- ✓ Protocol submission/evaluation: INVIMA forms (F) and guidelines (PM)
- ✓ GCP certification/ inspections (Sites, EC and Labs)
- ✓ EC: responsibilities, administrative and operative organization for clinical research
- ✓ Laboratories: requirements for clinical research
- ✓ Safety information reports for clinical research
- ✓ Investigational product management and labelling

Sites changes

SITES / LABS/ Ethics Committe : Sponsors/CRO support

1) 6 months of timeline to present the gradual plan to get the certification in GCP (2008)
2) 2 Years for the implementation of the gradual plan
3) Sites become an IPS (facilites, procedures, staff changes) and get the IPS certification
4) INVIMA visits to provide certifications for 5 year (2010… up to date).

Investment: Investigators association, find locations, new facilities (Pharmacy, depot, administrative office, archiving), staff training , new personnel within the site staff (Bacteriologist, pharmaceutical chemist, nurses, pharmacist)

Before 2008

Implementation Res. 2378

Today

Protocol evaluation

- To submit according to SEMPB calendar (2 months before the meeting)
- 2 photocopies of the dossier (200 pages per volume)
- 1CD with all related forms and Documents
- Protocol, related documents, investigators and institution must be approved by EC
- Payment of 2000USD

***SEMPB**: (Specialized Board of Drugs and Biological Products)
Pharmacological aspects
Concept provided in an act

- Protocol
- Investigator´s Brochure
- Supplies Importation
- Samples Exportation

GCP specialized group:
Administrative and operational aspects
Concept provided INVIMA web page

- Amendments
- ICF
- Site (IPS)
- Investigators/staff
- Other Documents:Diaries, questionaries

***SEMPB**: Specialized Board of Drugs and Biological Products

Protocol evaluation (SEMPB)

Protocol

F84-PM01-RS

PM01-RS-G36

- **Part I:** General information /Sponosor
- **Part II:** EC protocol, ICF and IB evaluation
- **List of documents:** Protocol, IB, ICF, recruitment material. diaries, PI CV and certifications including GCP , IRB approval letter, Insurance

Supplies Importation

F81-PM01-RS

PM01-RS-G42

- Quantities rational / per visit (20% extra)
- Certificate of free sale
- GMP
- Stability evaluation, Lots and CoA (A note can be sent if it is not available at that time)

Blood Sample Exportation

F82-PM01-RS

PM01-RS-G42

- Contact data of Central laboratory
- Type of sample
- Time and place where samples will be stored
- Exportation propose

Investigators Brochure

F83-PM01-RS,

PM01-RS-G43

- For new/updated versions

Protocol evaluation (GCP)

Site /IPS

F78-PM01-RS

PM01-RS-G40.

- EC approval letter of the institution(site), laboratories and other services where the protocol is going to be conducted
- Site GCP Certification
- IPS Certification (Lab, site and other services)

Investigators

F79-PM01-RS

PM01-RS-G41.

- EC approval letter of the PI specifying the time dedicated to the trials number of trials that is participating
- PI and SI: CV, medical license, ID, and professional certifications, GCP training
- PI: at least 3 years of clinical experience and 2 in clinical research

ICF

F76-PM01-RS

PM01-RS-G38

- For new/updated versions

Safety Reports

- **Res. 2010020508**: SAEs, AEs and SUSARs reporting. Annual safety report **2010**
- **Res. 2011020764,** derogates previous Res of 2010: Changes in timelines, definitions and requirements. **2011**

Local SAEs

Initial ,First FUP, Close report
F38-PM02-IVC

International AEs Expected SAEs

Anually: Investigator´s Brochure

SUSARs

PI: 20 days
EC: 15 days
INVIMA every 2 months
F-181-PM02-IVC

Annual Safety Report

F-180-P02-IVC

Local Special Requirements

Local Special Requirements: ICF

Inform Consent Process

Res. 8430

Under 6 years

- Legal Representative signs the ICF
- Documents: copy of the participant´s civil register and representative´s ID
- Witness: 2 independent

6 – 17 years

- Legal Representative signs the ICF
- psychological evaluation
- Inform Assessment Form
- Documents: copy of the participant´s civil register/ID and representative´s ID
- Witness: 2 independent

> 18 years

- Participant signs the ICF
- Documents: copy of participant´s ID
- Witness: 2 independent

Local Special Requirements: ICF

Inform Consent Process

Res. 8430

Mentally disabled/ Unconscious*

- Legal Representative sign the ICF
- Documents: copy of participant ID and representative ID
- Witness: 2 independent
- *Once the participant is recovered they must sign a new ICF

Illiterate

- Participant puts her/his finger print as signature
- Documents: copy of participant´s ID
- Witness: 2 independent +1 who reads the ICF and signs

subordinate

- In the EC meeting must participate one representative of the population
- Participant signs the ICF
- Documents: copy of participant´s ID
- Witness: 2 independent

Local Special Requirements : Labeling

IP Labelling
PM01-RS-G45

- Placebo and Comparative
- Spanish
- **Trial code**
- **Product name and concentration: placebo/xxxxx**
- **Pharmaceutical form, route of administration** and number of units (if applicable).
- **Lot number and due date**
- Storage conditions.
- Subject identification code when applicable participant and visit number.
- **Name**, address and telephone number of the **sponsor**.
- The legend "drug for use only in clinical trials."
- The words "Keep out of reach of children

Minimum requirements if there is not space in the package (vials, Blisters). However in the second package all the information must be written

Local Special Requirements: Deviations/Contract

Deviations
PM01-RS-G45

- Major and Critical reported via e-mail within 15 days after their knowledge

Contracts
PM01-RS-G46

- Budget reviewed by EC
- Institution/Investigator
- Evaluated by EC and additional agreements (Labs and other services)

Local Special Requirements: FU visits/Placebo

INVIMA FU Visits
PM01-RS-G45

- No announcement
- To ensure GCP certification maintenance
- To verify correct documentation of SAE´s
- To ensure document management/archiving
- To very the ICF process
- IP management
- Final report to implement actions plan or not

Placebo
(EC)

- It is allowed since there is not a standard treatment available
- Justification letter is NOT Necessary if the protocol has it

Extension Treatment
(ICH-GCP)

- INVIMA mention that ICH must be followed and Investigators must sign as a compromise
- However there is not a specific local requirement but some EC request it

Local Special requirements : Ethics Committee

- No Central EC
- GCP certification by INVIMA
- EC has to approve any document before INVIMA submission
- Institution EC for clinical research
- Sites can use EC from other institutions or an independent IRB

Other requirements

✓ Phase IV trials

- They need EC approval
- IC if there is an intervention (minimal)
- INVIMA protocol approval is not required
- If blood samples are going to be sent out of the country, the exportation requires the approval of INVIMA

✓ Amendments

- Must be approved by IRB to be implemented
- INVIMA just requires the notification

✓ Insurance

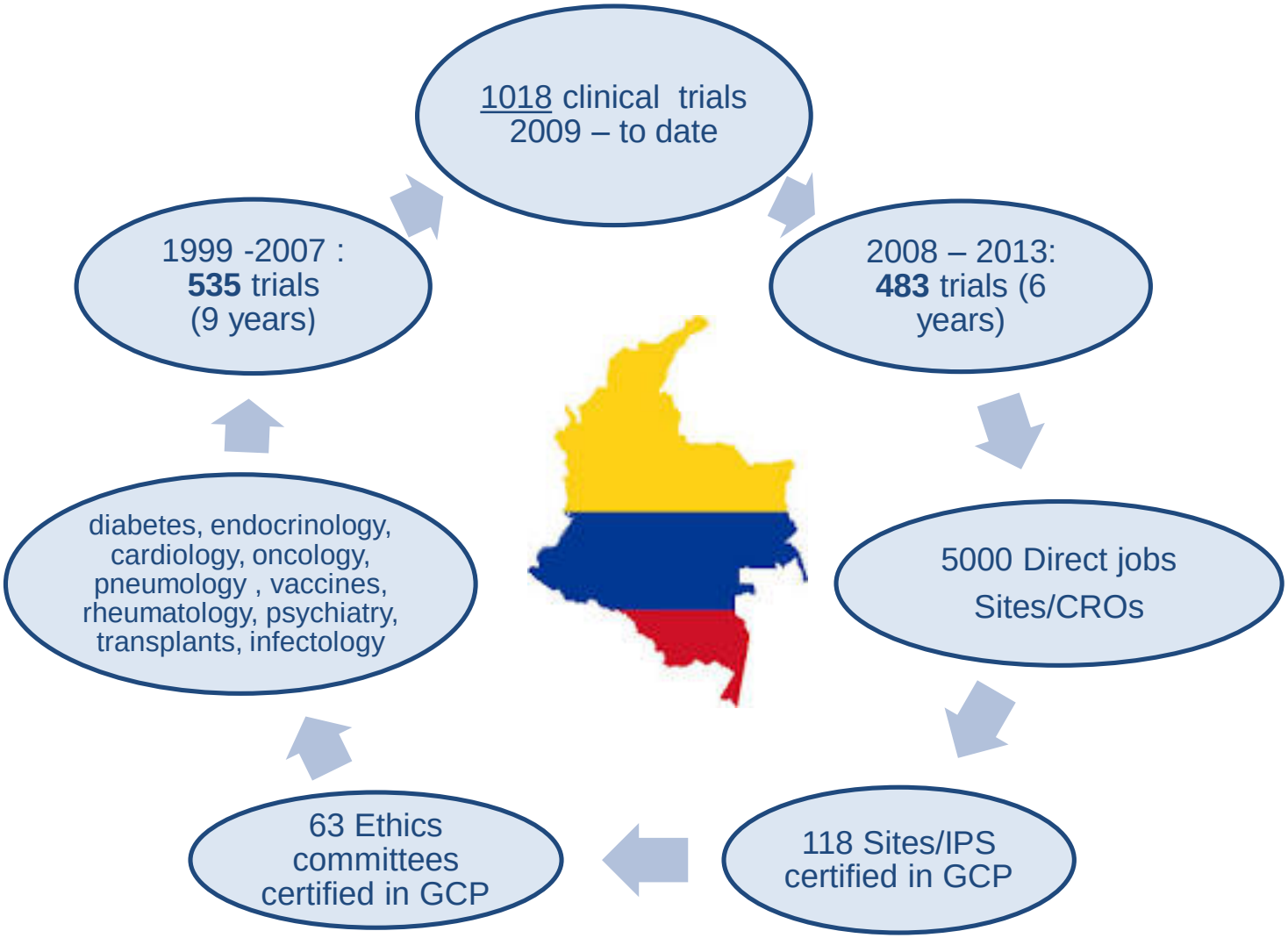
- It could be global or local policy, it is not specified in the regulation
- Contractual and extra contractual policy for associated adverse events attributable to the IP or trial procedure
- It has to be valid until the trial is closed in Colombia

Other requirements

- ✓ **Trial FSFV**
  - Protocol approved EC and INVIMA
  - First site approved by INVIMA
  - Additional sites can start with the EC approval and INVIMA notification
- ✓ **Import license**
  - Investigational product, comparative and placebo
  - Devices: new or used
  - Laboratory supplies
  - Has a validity period of six months
- ✓ **Renewal of protocol approval**
  - Annually
  - EC and INVIMA

What we have

What we have to date



What we have to date

- Open communication with INVIMA and collaboration through Clinical research associations such as:

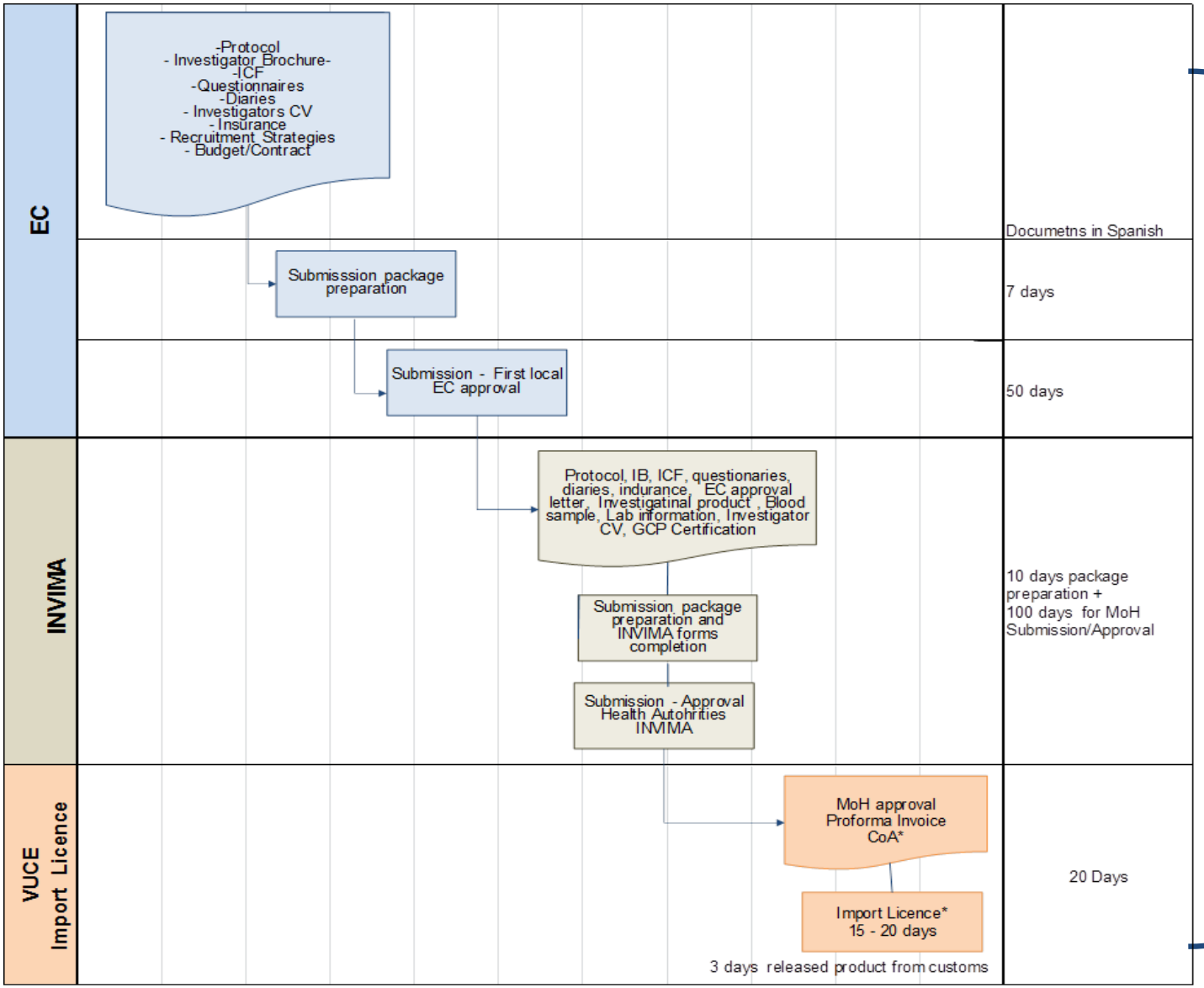
AVANZAR Asociación para el avance de la investigación

ACIC Asociación Colombiana de Centros de investigación Clinica

AFIDRO Asociación de laboratorios farmacéuticos de investigación y desarrollo

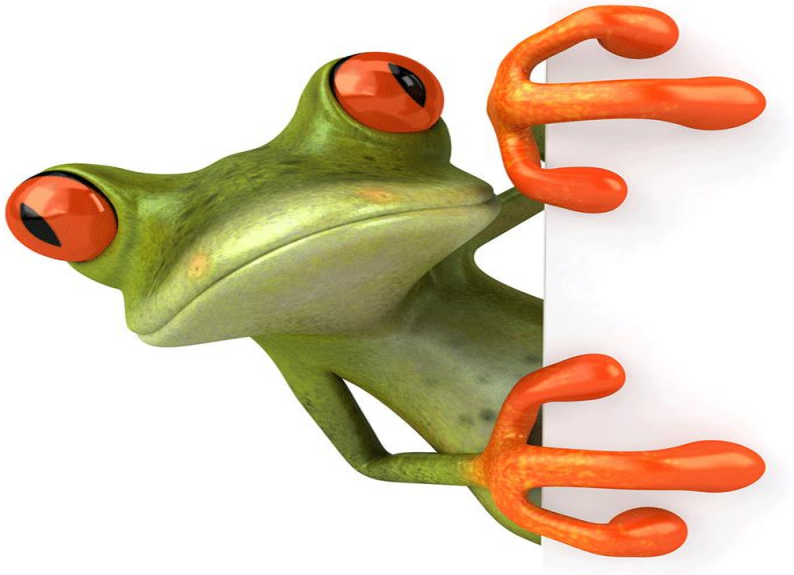
Regulatory timelines and Pathway

Submisson Pathway



A lesson ...

... in jumping to CONCLUSIONS



Advantages Clinical Research in Colombia

- ✓ Support of Regulatory Authorities to promote clinical research in Colombia
- ✓ Consolidated regulatory environment that provides legal security to clinical research in Colombia
- ✓ Strong relationship between participant and physician that allows high adherence
- ✓ Good acceptance by the community to participate in clinical research
- ✓ Centers and laboratories with all facilities and certified in GCP capable of delivering data with high quality standards
- ✓ Professional personnel trained and with experienced in clinical research
- ✓ Significant growth in clinical research in the recent years. Most of the CROs have established legal entities in Colombia.

Oportunities in Clinical Reserarch in Colombia

- ✓ Enhance the way that INVIMA communicates the updates to the guidelines, forms and other documents related to clinical research
- ✓ Logistics sufficient of the INVIMA to optimize response times and regulatory processes
- ✓ Creation of new research centers that will address new population in order to have new alternatives too meet the trials demand for in Colombia.
- ✓ Support of the pharmaceutical companies, CROs and associations to promote clinical research and motived new institutions to include clinical research among their services
- ✓ Postgraduate education in clinical research supported by Universities and the Government

• RESOURCES

INVIMA Web Page

http://www.invima.gov.co/index.php?option=com_content&view=article&id=991&Itemid=326

- Estado de la Investigación Clínica en Colombia relacionado con medicamentos en el desarrollo de nuevas moléculas. Adriana Parra. Tesis de Grado de Maestría, Universidad Nacional de Colombia, 2011

- Impact of clinical research in the development of a country, Dora Molina. Acta Médica Colombiana, Vol. 37 Nº 4 ~ 2012


obrigado
Dank U
Merci
mahalo
Köszi
спасибо
Grazie
Thank you
mauruuru
Takk
Gracias
Dziękuję
Děkuju
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