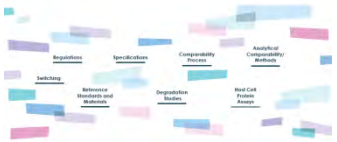


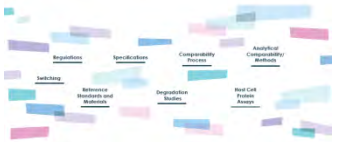
Johanna Andrea García Cortes, MSc, Colombia

- Professional Specialist, Medicamentos y Productos Biológicos, Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA), Colombia

GaBI Scientific Meetings

Second Colombian Scientific Meeting on Quality Assessment of **BIOSIMILARS/SIMILAR BIOTHERAPEUTIC PRODUCTS**

15 August 2017, Hiilton Bogotá, Colombia



Biosimilars regulations in Colombia

Johanna Andrea García Cortes, MSc

15 August 2017

GaBi
GENERICS AND BIOSIMILARS INITIATIVE
Building trust in cost-effective treatments

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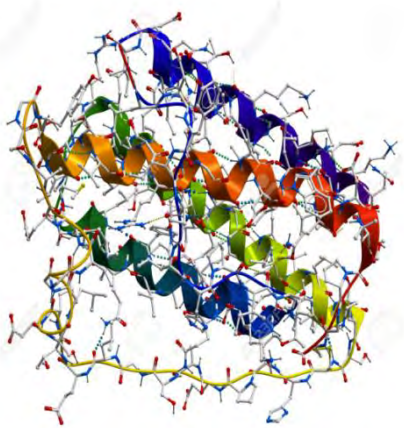
PPCI
Pro Pharma Communications International

Instituto Nacional de Vigilancia de Medicamentos y Alimentos.

Biosimilar Regulation in Colombia

Johanna Andrea Garcia, MSc , Biological Products Coordinator



CONTENTS

Current Regulation (Before Implementation)

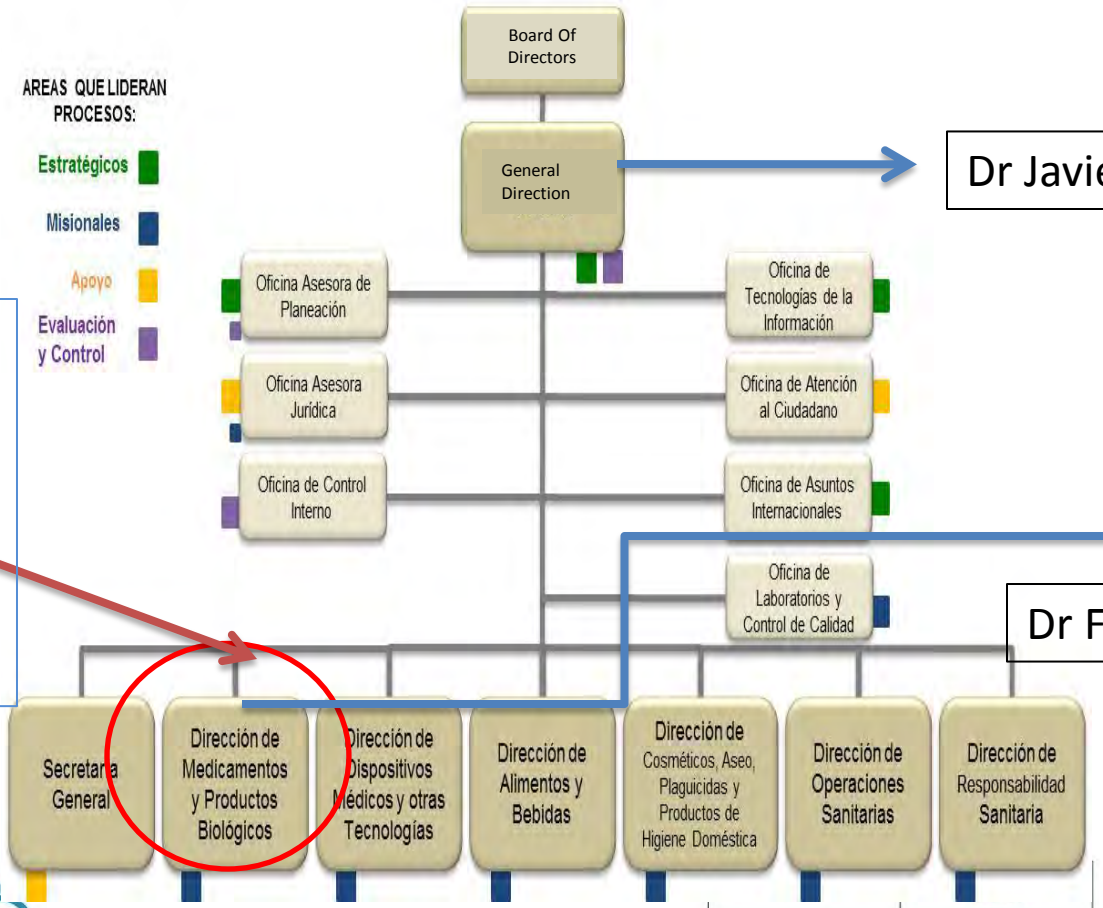
Changes in the Study Process due to Implementation

Full Case File Approach

Comparability Approach

Abbreviated Comparability Approach

INSTITUTIONAL CHART



Dr Javier Guzman

Medicines and Biological Products Direction

Dr Francisco Sierra

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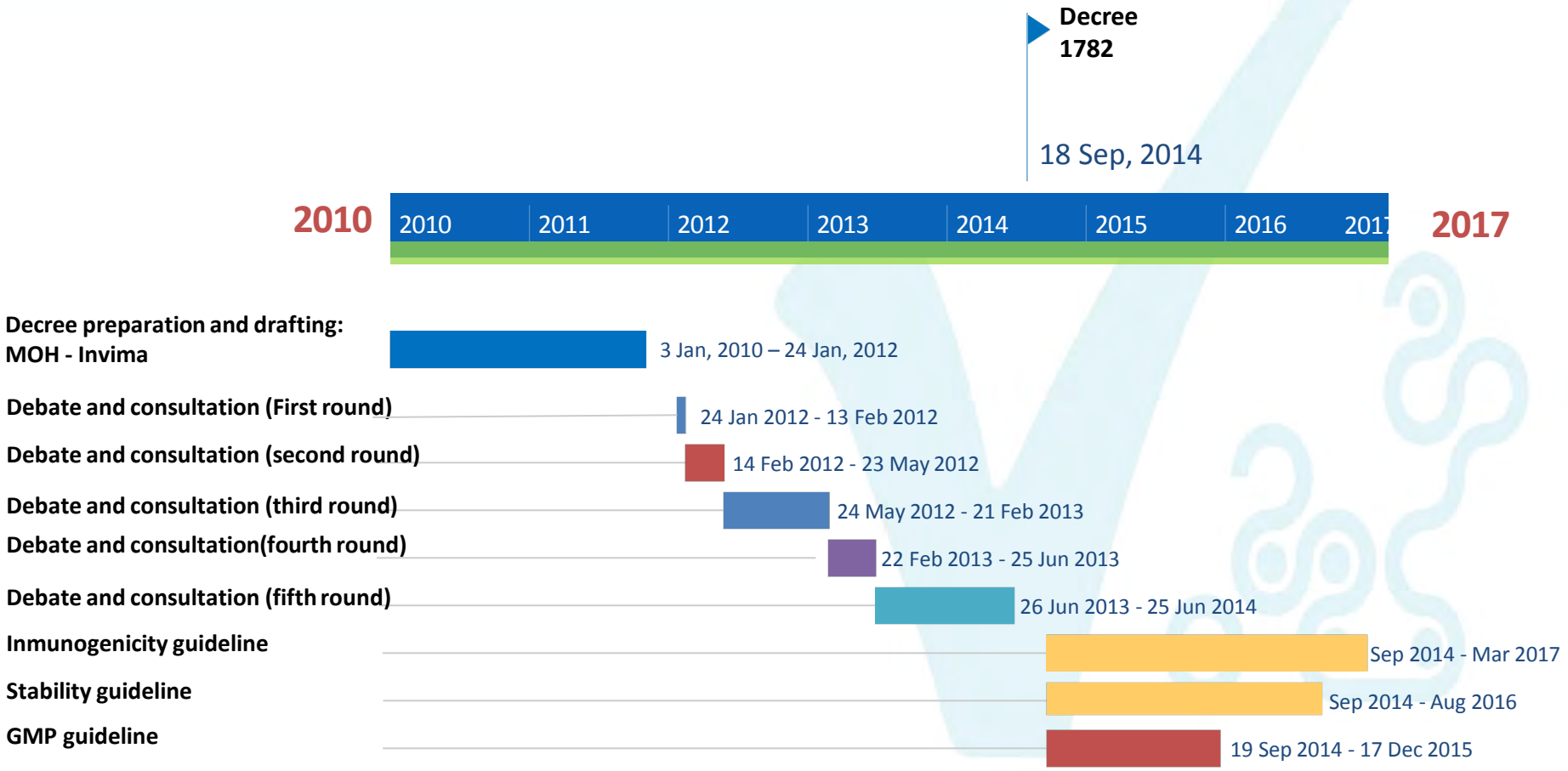
MARKETING AUTHORIZATION PROCESS TODAY

Pharmacological Evaluation

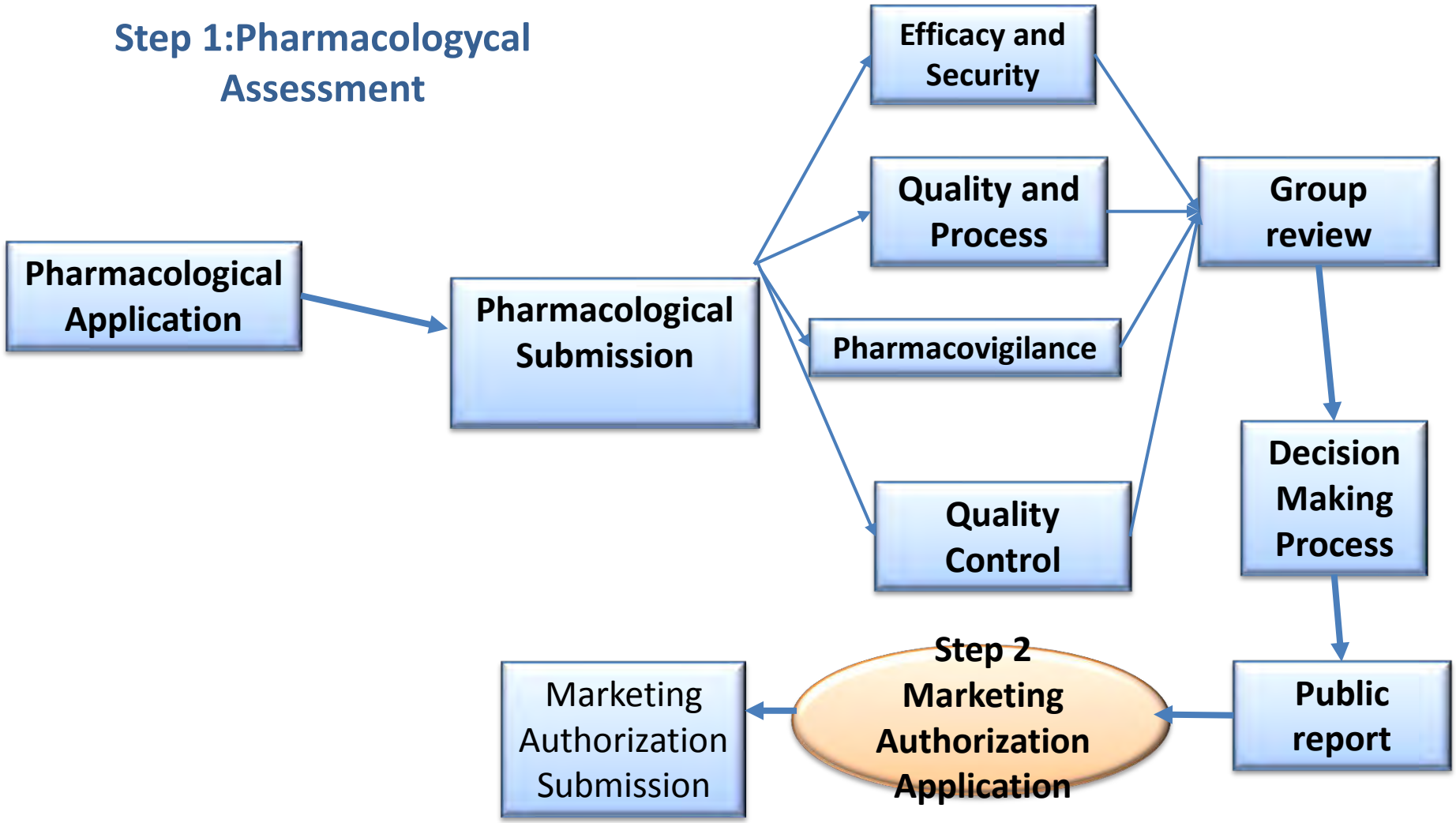
Legal and Quality and process Assessment

Laboratory test (Batch Release)

Regulatory timeframe



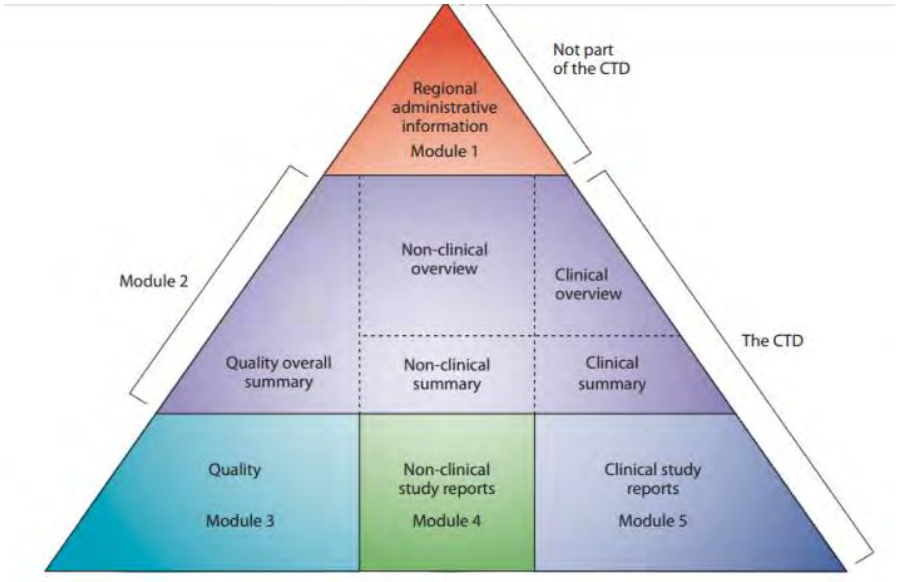
CHANGES IN THE STUDY PROCESS DUE TO IMPLEMENTATION



3 PATHWAYS FOR EVALUATION

FULL DOSSIER CASE	COMPARABILITY	ABBREVIATED COMPARABILITY
• Manufacturing Process and Production Place • Expression System • Biological Identity • Potency and Purity • Physicochemical Properties • Biological Activity • Immunogenicity		

COMPLETE DOSSIER APPROACH



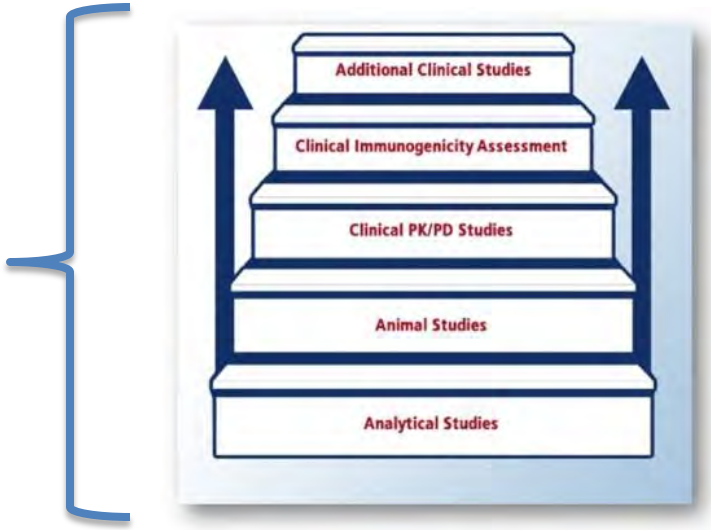
Designed in Biologicals for:

1. New Molecules, New Developments

- Module 1 • Administrative
- Module 2 • Summary
- Module 3 • Quality
- Module 4 • Non Clinical
- Module 5 • Clinical full dossier

ICH Topic M 4 Q Common Technical Document for the Registration of Pharmaceuticals for Human Use

Comparability Approach



Designed in Biologicals for:

1. Patent-expired molecules

2. Molecules that are compared against a reference product

- Module 1
  - ADMINISTRATIVE
- Module 2
  - Summary
- Module 3
  - Quality + Comparability
  - Full
- Module 4
  - Non Clinical + Comparability
- Module 5
  - Clinical Reduce + Comparability

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EMA AND FDA: Abbreviated comparability

In specific circumstances, a confirmatory clinical trial may not be necessary. This requires that similar efficacy and safety can clearly be deduced from the similarity of physicochemical characteristics, biological activity/potency, and PK and/or PD profiles of the biosimilar and the reference product. In addition, it requires that the impurity profile and the nature of excipients of the biosimilar itself do not give rise to concern.

EMA CHMP/437/04 Rev

U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov

General Requirements

A 351(k) application must include information demonstrating biosimilarity based on data derived from:

- **Analytical studies** demonstrating that the biological product is "highly similar" to the reference product notwithstanding minor differences in clinically inactive components;
- **Animal studies** (including the assessment of toxicity); and
- A **clinical study or studies** (including the assessment of immunogenicity and pharmacokinetics (PK) or pharmacodynamics (PD)) that are sufficient to demonstrate safety, purity, and potency in 1 or more appropriate conditions of use for which the reference product is licensed.

FDA may determine, in its discretion, that an element described above is unnecessary in a 351(k) application.

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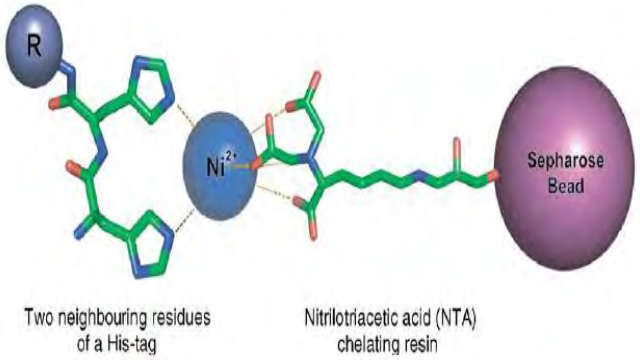


Rachel E. Sherman, MD, MPH
Associate Director for Medical Policy
Center for Drug Evaluation and Research

ABBREVIATED COMPARABILITY APPROACH

Which Products Can Choose the Abbreviate Comparability Approach

Products Containing Active Pharmaceutical Ingredients Which are:

- Sufficiently Characterized
- Those Which have a Safety and Efficacy Well-defined Profile and are Well-documented
- Those Which have Strong Clinical Experience
- Those Which have Strong Pharmacovigilance

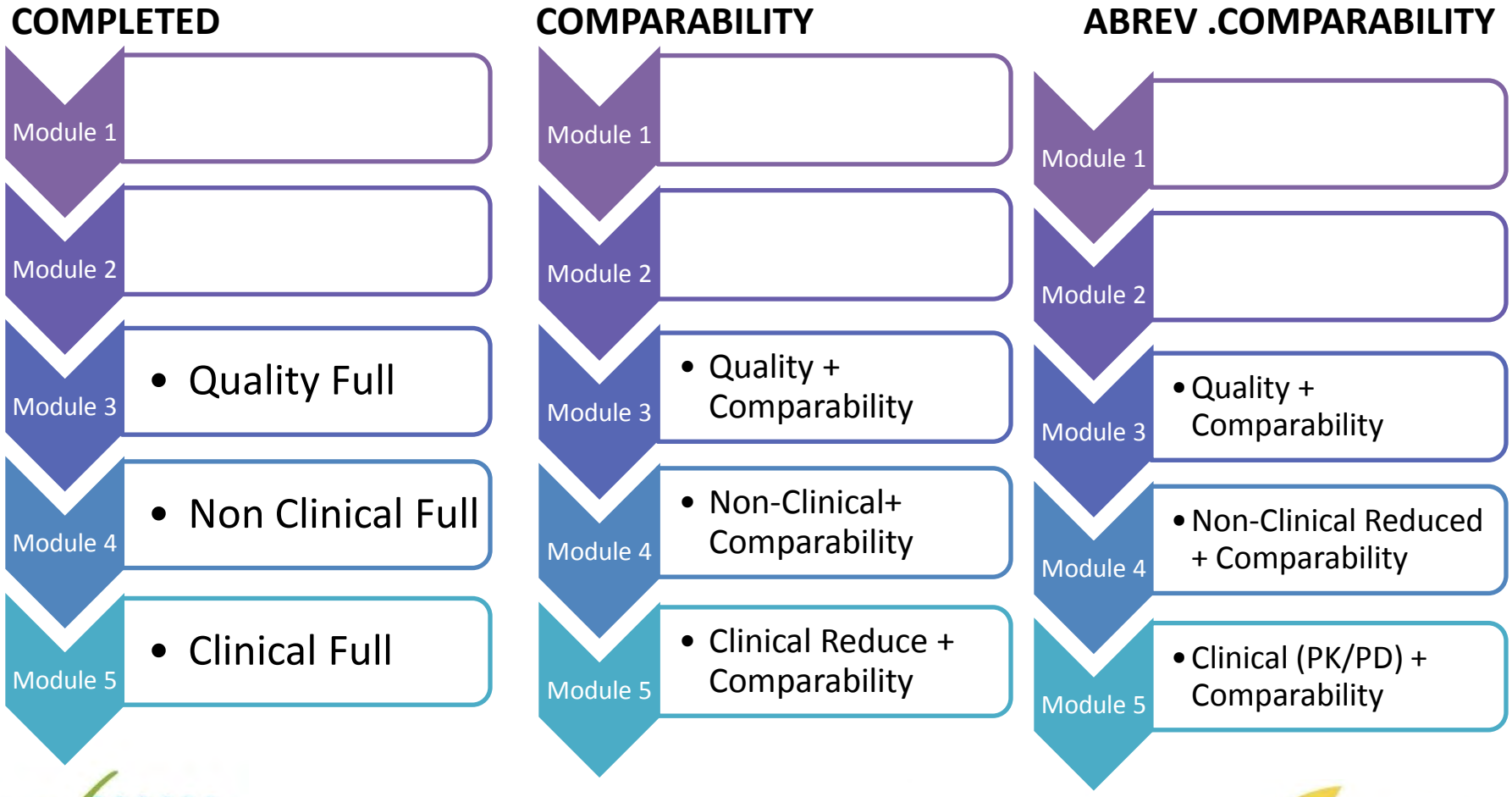
ABBREVIATED COMPARABILITY APPROACH

2. Comparability way

3. **Abbreviated comparability**

- Module 1 •Administrative
- Module 2 •Summary
- Module 3 •Quality + Comparability
- Module 4 •Non-Clinical Reduced + Comparability
- Module 5 •Clinical (PK/PD)

DIFFERENCES AMONG THE THREE APPROACHES



Thank You

www.invima.gov.co
Carrera 10 64-28 Bogotá - Colombia
Teléfono conmutador: 2948700

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