



**IMDRF** International Medical  
Device Regulators Forum

# **REGULATION OF MEDICAL DEVICES IN COLOMBIA**

## **“INTERACTION BETWEEN PRE AND POST MARKET EVALUATION”**

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## **CONTENT**

**I. Effectiveness Evaluation of Medical Devices**

**II. Surveillance Pre and Post Market approach for Medical Devices.**

**III. Pre and Post Market Interaction in Intensive Surveillance.**

**IV. Surveillance Evolution in Colombia**

- i. Spontaneous Surveillance Results**
- ii. Proactive Surveillance Results**
- iii. Intensive Surveillance Results**



## I. EFFICACY EVALUATION OF MEDICAL DEVICES

### PRE MARKET ASSESSMENT

DESIGN AND DEVELOPMENT

MANUFACTURING

### MANUFACTURER

#### scientific and Technical Evaluation:

- ✓ Quality
- ✓ Safety
- ✓ Performance



**EFFICACY**

#### Technical Requirements:

1. Medical Device description
2. technical studies and analytical tests.
3. Sterilization Method, when applicable.
4. Waste disposal Method or disposal of the product
5. Labels and Inserts.
6. Risk IIa, IIb and III Scientific Information, Risk Analysis
7. Biocompatibility studies
8. Risk IIb and III clinical studies on the use of the product to demonstrate safety and effectiveness.
9. Certification Commitment: deliver to the end user the operating manuals (user) and maintenance, available in Spanish language.

### MARKETING AUTHORIZATION

HEALTH REGISTRATION

MARKETING PERMISSION



**POST MARKET SURVEILLANCE  
TECHNOSURVEILLANCE  
NATIONAL PROGRAM**

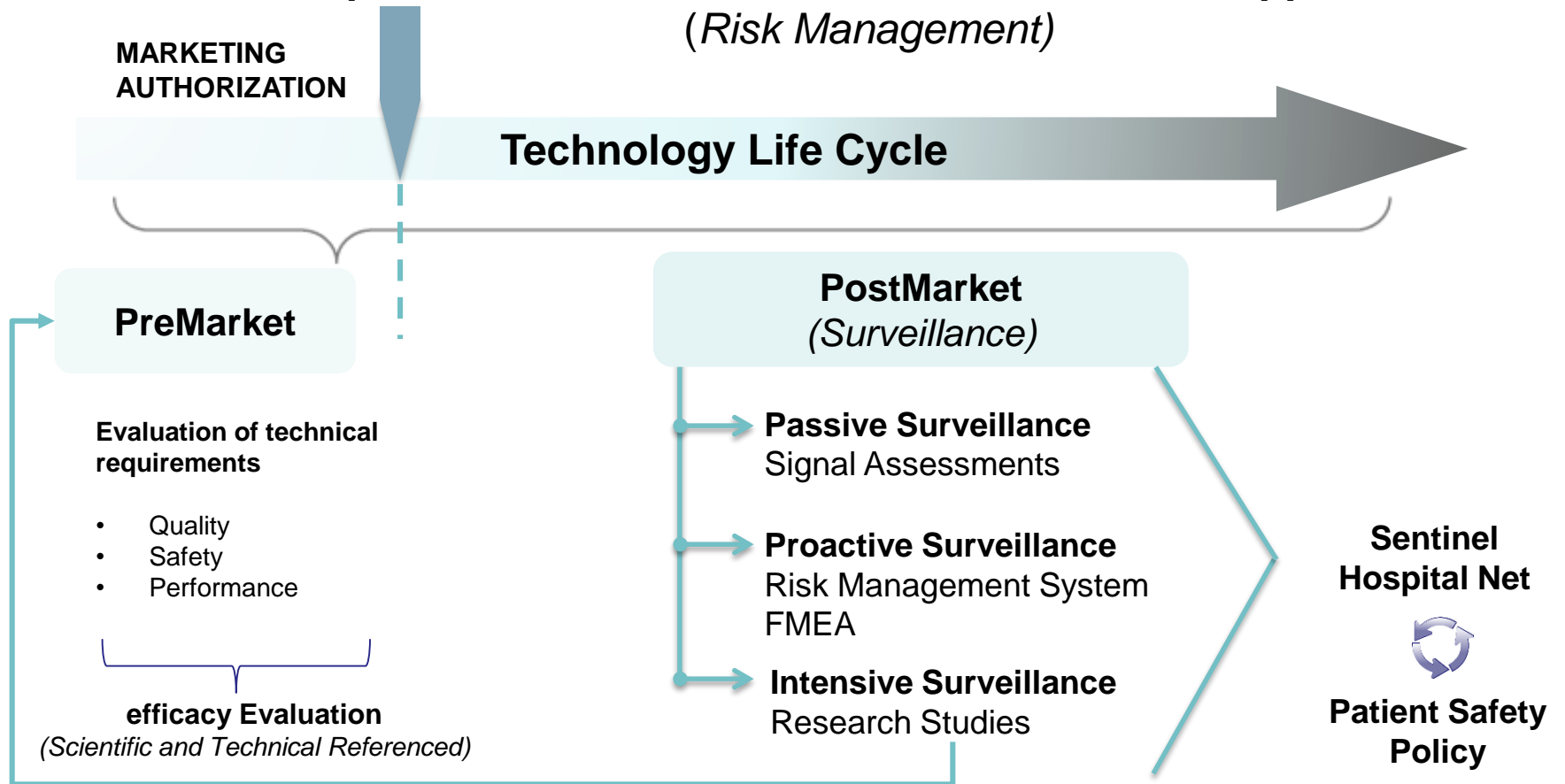


**EFFECTIVENESS**



## II. SURVEILLANCE PRE AND POST MARKET APPROACH FOR MEDICAL DEVICES.

**NRA - Inspection, Surveillance and Control with Risk Approach**  
(*Risk Management*)



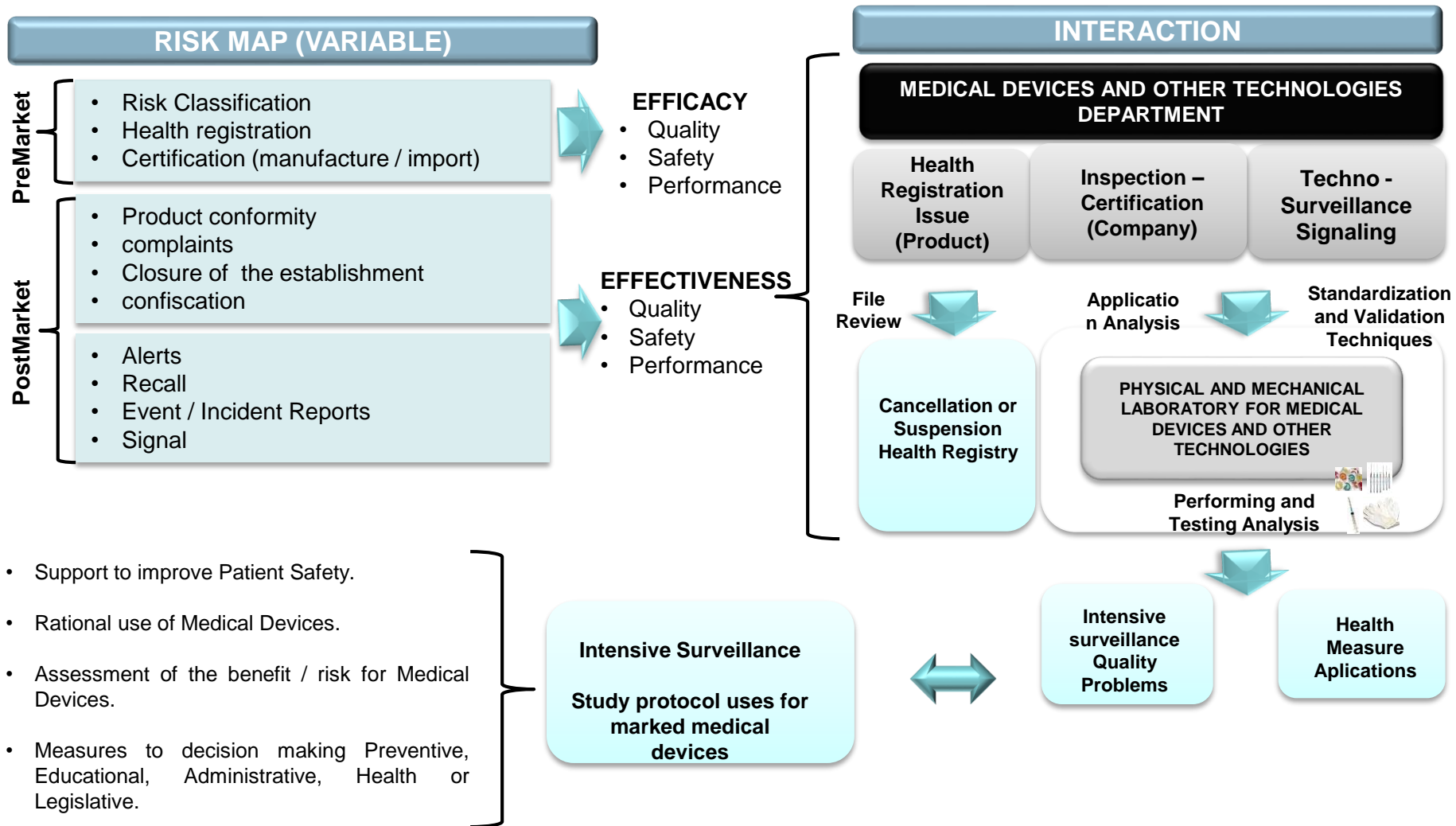
(*Risk Communication*)

**NRA - Decision making in health and risk mitigation actions**



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## III. PRE AND POST MARKET INTERACTION IN INTENSIVE SURVEILLANCE.





## IV. SURVEILLANCE EVOLUTION IN COLOMBIA

### STRATEGIC ALLIANCE



FACULTY OF MEDICINE  
CLINICAL RESEARCH  
INSTITUTE  
NATIONAL UNIVERSITY OF  
COLOMBIA

**Active Surveillance**

(Reactive)  
WHO, 1968

**Passive Surveillance**  
(Spontaneous and  
Voluntary)

Resolution 4816/2008,  
Article 30.

**Proactive Surveillance**

(Anticipate).  
Defining 'Surveillance' in  
Drug Safety 2012  
Jeffrey K. Aronson,  
Manfred Hauben  
and Andrew Bate  
(SGRC)\_FMEA

**Intensive Surveillance**

(Research Protocols  
for MD)  
OPS. Program  
Research Grants  
(PRG).  
Guide to Writing a  
research protocol.

### RESEARCH PROTOCOLS

Implantable Medical Devices (4).

Non Implantable Medical Devices  
difficult Traceability (3).

2008

2011

2012

2013

2014

2015

2016



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**2011                      2012                      2013                      2014                      2015**

**Spontaneous Surveillance**

**Proactive Surveillance**

	2011	2012	2013	2014	2015
	* Technosurveillance Net: <b>1082</b> Event Analisis: <b>1422</b> Alert Analisis: <b>86</b>	Technosurveillance Net: <b>1036</b> Event Analisis: <b>1644</b> Alert Analisis: <b>38</b>	Technosurveillance Net: <b>2640</b> Event Analisis: <b>3288</b> Alert Analisis: <b>196</b>	Technosurveillance Net: <b>5846</b> Event Analisis: <b>5842</b> Alert Analisis: <b>284</b>	Technosurveillance Net: <b>7416 (T:20.127) (67%)</b> Event Analisis: <b>6478 (T:20.860)</b> Alert Analisis: <b>311</b>
	Data Base TV Reports Parameterization ISO 19218:2011	Report Format: User, Hospitals, Health Secretaries, Importers.	Implementation Method Signalling Risk Map	Signalling Analisis MD Data Base Signaled and Prioritized.	Modernization Web Application.
	Scientific Literature Review on Clinical Risk Management - Failure Mode Effect Analysis	FMEA Pilot Test in 5 Hospitals Implementation Operative Manual	FMEA Workshops directed to 180 hospitals. Followup tools FMEA.	Implementation of FMEA Method in 30 Hospitals. <b>16 FMEA**</b> implemented with Medical Devices.	FMEA Implementation in 11 new Hospitals and followup in 30 Hospitals. <b>(T:41)</b>
				Development of the Virtual Learning platform.  8 virtual design modules.	17 professionals trained as Virtual tutors. 636 Virtual training Referring  7388 Site training Referring

**Health Education  
(Virtual Net INVIMA)**

**Intensive  
surveillance and  
Sentinel Net**

Research with (4)  
Medical Devices  
implantable signalled  
in **8 Hospitals** –  
formed by Sentinel  
Net. \*\*\*

\* <https://www.invima.gov.co/images/pdf/tecnovigilancia/red-nal-tecnovigilancia/ESTADISTICASDICIEMBRE2015.pdf>  
 \*\* <https://www.invima.gov.co/avance-de-la-vigilancia-proactiva-en-colombia>  
 \*\*\* <https://www.invima.gov.co/vigilancia-intensiva-en-colombia>



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## ii. PROACTIVE AND INTENSIVE SURVEILLANCE RESULTS

### 41 HOSPITALS IN THE SENTINEL NET WITH CLINICAL RISK MANAGEMENT SYSTEM "FMEA" (PROACTIVE) (2014 - 2015)

#### 16 FMEA WITH MEDICAL DEVICES (2014 - 2015)

1. Hospital Pablo Tobón Uribe\*
2. Hospital General de Medellín\*
3. Hospital Universitario San Vicente Fundación\*
4. IPS Universitaria León XIII\*
5. EMMSA Clínica Especializada
6. Clínica Versalles
7. IPS Confamiliar- Risaralda

8. Hospital Universitario del Valle
9. Centro Médico Imbanaco
10. Valle de Lili Fundación\*
11. Hospital Susana López
12. Hospital Pediátrico Los Ángeles
13. Hospital Civil de Ipiales
14. Hospital Universitario Departamental de Nariño

15. Diacorsa- Instituto del Corazon Ibague
16. ESE Hospital Hernando Moncaleano

17. Clínica Meta
18. Hospital de Yopal

36. ESE Hospital Niño Jesus de Barranquilla
37. IPS Universitaria Camino Adelita de Char\*
38. IPS Confamiliar - Cartagena
39. Clínica Zayma
40. ONCOMÉDICA S.A.
41. Centro Oftalmológico CARRIAZO\*

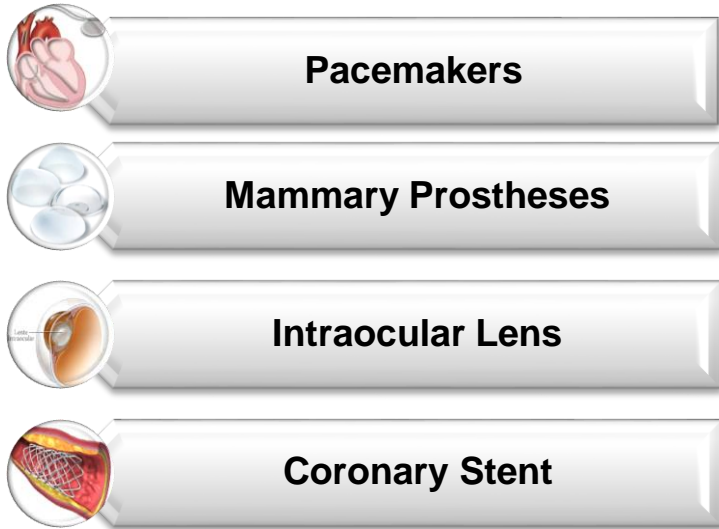
19. Hospital de San José - SCB
20. Javesalud IPS
21. Clínica del Country
22. Hospital Infantil de San José
23. Virrey Solís IPS S.A.
24. Centro Dermatológico Federico Lleras Acosta
25. Centro Policlínico del Olaya
26. Hospital Pablo VI Bosa
27. Hospital de la Misericordia
28. ESE Hospital Santa Clara
29. Clínica Chía
30. Hospital San Rafael de Facatativá
31. Fundación Cardiovascular de Colombia
32. Fundación Oftalmológica de Santander \*
33. Hospital Universitario de Santander
34. Hospital Regional de Duitama
35. Hospital San Rafael de Tunja

### 8 HOSPITALS WITH INTENSIVE SURVEILLANCE (2015)\*



## iii. INTENSIVE SURVEILLANCE RESULTS

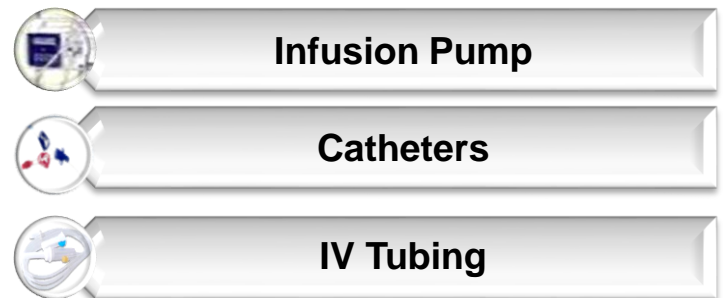
### 2015



- Review of 473 Clinical Case Studies of 773 implantable devices obtaining 189 valid reports.
- Causes most frequently associated with adverse events:
  - **820** Patient Condition. **(51%)**
  - **510** abnormal or unexpected physiological response. **(18%)**
  - **780** Non device related. **(8,1%)**
  - **790** Another cause of event. **(7,9%)**
  - **930** Unidentified definite or non probable given cause. **(7,0%)**
  - **810** Anatomy / Physiology patient where the average design of the device is inappropriate based on the anatomy / physiology of the patient. **(5,8%)**
  - **770** Insanitary conditions, a failure of the medical device by improper hygienic condition of the User. **(1,2%)**
  - **500** Abnormal use, omission of an act by the user or operator. **(1,0%)**

- Usage study protocol for each non-implantable medical device with difficult marked traceability.
- Standardization of techniques for conformity assessment quality Catheters and IV Tubing. (Laboratory Devices).
- National Security Reports focused on risk containment approach and rational use of medical devices

### 2016





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# THANKS FOR YOUR ATTENTION

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