REGULATION OF MEDICAL DEVICES IN COLOMBIA

“INTERACTION BETWEEN PRE AND POST MARKET EVALUATION”

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CONTENT

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


IV. Surveillance Evolution in Colombia
   i. Spontaneous Surveillance Results
   ii. Proactive Surveillance Results
   iii. Intensive Surveillance Results
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.

4725 Decree of 2005. Articles 18, 24 and 38

Efficacy: When technologies work in optimal conditions.
II. SURVEILLANCE PRE AND POST MARKET APPROACH FOR MEDICAL DEVICES.

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

MARKETING AUTHORIZATION

Technology Life Cycle

PreMarket

Evaluation of technical requirements
- Quality
- Safety
- Performance

efficacy Evaluation (Scientific and Technical Referenced)

PostMarket (Surveillance)

Passive Surveillance
Signal Assessments

Proactive Surveillance
Risk Management System
FMEA

Intensive Surveillance
Research Studies

Sentinel Hospital Net
Patient Safety Policy

(Risk Communication)

NRA - Decision making in health and risk mitigation actions
III. PRE AND POST MARKET INTERACTION IN INTENSIVE SURVEILLANCE.

**RISK MAP (VARIABLE)**

- Risk Classification
- Health registration
- Certification (manufacture / import)
- Product conformity
- complaints
- Closure of the establishment
- confiscation
- Alerts
- Recall
- Event / Incident Reports
- Signal

**INTERACTION**

**Efficacy**
- Quality
- Safety
- Performance

**Effectiveness**
- Quality
- Safety
- Performance

**MEDICAL DEVICES AND OTHER TECHNOLOGIES DEPARTMENT**

- Health Registration Issue (Product)
- Inspection – Certification (Company)
- Techno-Surveillance Signaling

- File Review
- Applicatio n Analysis
- Standardization and Validation Techniques

**Intensive Surveillance**

Study protocol uses for marked medical devices

- Support to improve Patient Safety.
- Rational use of Medical Devices.
- Assessment of the benefit / risk for Medical Devices.
- Measures to decision making Preventive, Educational, Administrative, Health or Legislative.
IV. SURVEILLANCE EVOLUTION IN COLOMBIA

Proactive Surveillance
(Reactive)
WHO, 1968

Active Surveillance
(Reactive)
Resolution 4816/2008, Article 30.

Pasive Surveillance
(Spontaneous and Voluntary)

WHO, 1968

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).
IMDRF International Medical Device Regulators Forum

### Spontaneous Surveillance

<table>
<thead>
<tr>
<th>Year</th>
<th>Event Analysis</th>
<th>Alert Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>Technosurveillance Net: 1082</td>
<td>Alert Analysis: 86</td>
</tr>
<tr>
<td>2012</td>
<td>Technosurveillance Net: 1036</td>
<td>Alert Analysis: 38</td>
</tr>
<tr>
<td>2013</td>
<td>Technosurveillance Net: 2640</td>
<td>Alert Analysis: 196</td>
</tr>
<tr>
<td>2014</td>
<td>Technosurveillance Net: 5846</td>
<td>Alert Analysis: 284</td>
</tr>
</tbody>
</table>

- Data Base TV Reports
- Parameterization ISO 19218:2011
- Implementation Method Signalling
- Risk Map
- Signalling Analysis MD Data Base Signalled and Prioritized.

### Proactive Surveillance

<table>
<thead>
<tr>
<th>Year</th>
<th>User, Hospitals, Health Secretaries, Importers.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>FMEA Pilot Test in 5 Hospitals Implementation Operative Manual</td>
</tr>
<tr>
<td>2012</td>
<td>FMEA Workshops directed to 180 hospitals. Followup tools FMEA.</td>
</tr>
<tr>
<td>2013</td>
<td>Implementation of FMEA Method in 30 Hospitals. <strong>16 FMEA</strong> implemented with Medical Devices.</td>
</tr>
<tr>
<td>2014</td>
<td>FMEA Implementation in 11 new Hospitals and followup in 30 Hospitals. (T:41)</td>
</tr>
<tr>
<td>2015</td>
<td>17 professionals trained as Virtual tutors.</td>
</tr>
</tbody>
</table>

- Modernization Web Aplication.
- Implementation of FMEA Method in 30 Hospitals.
- Development of the Virtual Learning platform.
- 8 virtual design modules.

### Health Education (Virtual Net INVIMA)

- Modernization Web Aplication.
- 8 virtual design modules.

### Intensive surveillance and Sentinel Net

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

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** [https://www.invima.gov.co/avance-de-la-vigilancia-proactiva-en-colombia](https://www.invima.gov.co/avance-de-la-vigilancia-proactiva-en-colombia)

ii. PROACTIVE AND INTENSIVE SURVEILLANCE RESULTS

41 HOSPITALS IN THE SENTINEL NET WITH CLINICAL RISK MANAGEMENT SYSTEM “FMEA” (PROACTIVE) (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 Pediatrico 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
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
36. ESE Hospital Niño Jesús de Barranquilla
37. IPS Universitaria Camino Adelita de Char*
38. IPS Confamiliar – Cartagena
39. Clínica Zayma
40. ONCOMÉDICA S.A.
41. Centro Oftalmológico CARRIAZO*

16 FMEA WITH MEDICAL DEVICES (2014 – 2015)

https://www.invima.gov.co/avance-de-la-vigilancia-proactiva-en-colombia
**iii. INTENSIVE SURVEILLANCE RESULTS**

### 2015

- **Pacemakers**
- **Mammary Prostheses**
- **Intraocular Lens**
- **Coronary Stent**

**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%)

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### 2016

- **Infusion Pump**
- **Catheters**
- **IV Tubing**

**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**

THANKS FOR YOUR ATTENTION

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