Regulatory Impact Analysis Guide

# Why conduct a **Regulatory Impact Analysis?**

Structure, key messages, and practical applications of the RIA Guide for the medical technology sector

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# Guide: Why conduct a Regulatory Impact Analysis?

**Purpose of the presentation**

**Present the structure, key messages, and practical applications of the *RIA Guide*.**

*A tool designed specifically for the medical technology sector.*

Key message

"

RIA is not a bureaucratic requirement. It is a tool to improve the quality of regulatory decisions.

# Why is RIA important in medical technologies?

## A sector with particular challenges

- → Accelerated technological innovation
- → Short product life cycles
- → High risks to public health
- → Timely access to new technologies

## The regulatory challenge · Finding the balance

**Safety**

of the patient

**Reasonable**

regulatory costs

**Innovation**

and competitiveness

*Three objectives that must coexist in every regulatory decision*

Excessive **regulation** can generate the same problems as insufficient **regulation**.

Document map

# Structure of the Guide

The document is organized into four modules that articulate principles, methodology, proportionality criteria, and operational tools.

**04**

**Main modules**

01 Module

## Foundations and principles

Purpose of evidence-based RIA · relevance for the sector · transparency, predictability, and focus on results · orientation toward quality and institutional change.

02 Module

## 9-stage RIA methodology

Problem → Objectives → Alternatives → International experience → Comparison of impacts and risks → Public participation → Implementation and monitoring → Ex post evaluation → Final report.

03 Module

## Complexity and proportionality

Simple RIA vs. complex RIA · criteria and decision thresholds to define the depth of the analysis.

04 Module

## Practical application and tools

Comparative cases · self-assessment checklist · standardized form · bibliographic references.

# RIA as a quality process

*The guide highlights three essential dimensions that define when an RIA truly adds value.*

01

## Formal quality

Compliance with the methodological stages suggested by the Guide.

02

## **Usefulness for decision-making**

RIA must effectively influence the final decision, not remain only on paper.

03

## Cultural change

RIA must not become a mere admi*nistrat*ive compliance checklist.

A high-quality RIA helps **question assumption**s and choose **better regulatory alternative**s.

# The 9 steps of RIA

*The step-by-step methodology, organized as a complete regulatory cycle.*

**Step 01**
Problem identification

**Step 02**
Definition of objectives

**Step 03**
Identification of alternatives

**Step 04**
International experience and impacts

**Step 05**
Comparison of impacts and risks

**Step 06**
Public participation

**Step 07**
Implementation and monitoring

**Step 08**
Ex post evaluation (ARR)

**Step 09**
Final report and communication

Diagnosis  Analysis  Implementation and evaluation

RIA accompanies the entire regulatory cycle, from problem identification to results evaluation.

# The five critical elements for a quality RIA

## 1

### Correctly define the problem

Do not confuse the problem with the absence of a rule.

## 2

### Set clear objectives

SMART and measurable objectives.

## 3

### Analyze alternatives

· Do nothing
· Non-regulatory alternatives
· Regulatory alternatives

## 4

### Use evidence

Data, technical analysis, and science.

## 5

### Plan future evaluation

Monitoring and evaluation of regulatory results.

From start to finish

**Solid diagnosis**
→ Results evaluation

A solid RIA begins with a **good diagnosis** and ends with **a results evaluation**.

# Think beyond traditional regulation

*The guide proposes a series of alternatives that begins with the least invasive options.*

**Level 4 · Greater intervention**
**Traditional regulation** — Obligations · restrictions · sanctions

**Level 3**
**Co-regulation** — Shared responsibilities **State · industry**

**Level 2**
**Self-regulation** — Codes of conduct · Sector commitments

**Level 1 · Less intervention**
**Non-regulatory alternatives** — Information · Education · Transparency

↑ *first consider the least invasive alternatives (base) before imposing obligations (top)*

Issuing a rule should be a **considered alternative, not** a predetermined conclusion.

# Simple RIA vs. complex RIA

Guiding principle

**Proportionality** — the analytical effort must be proportional to the expected impacts

Limited impact

## Simple RIA

- ✓ Well-defined operational problem
- ✓ Qualitative analysis
- ✓ Few alternatives to compare
- ✓ Light documentation

High impact · high uncertainty

## Complex RIA

- Multiple affected actors and markets
- Quantitative multicriteria analysis
- International benchmarking
- Systemic risks to evaluate

Not all problems require the **same level of analysis**.

# Practical cases presented by the guide

**Simple case**

## Grouping of implantable materials in orthopedics

Characteristics

1. **Operational problem**
   Clear and delimited nature
2. **Specific regulatory solution**
   Specific technical adjustment
3. **Qualitative analysis**
   Does not require quantitative models

**Complex case**

## Software as a medical device (SaMD)

Characteristics

1. **Cybersecurity risks**
   Critical component in clinical data
2. **Accelerated innovation**
   Very short update cycles
3. **International benchmarking**
   FDA, MDR, IMDRF
4. **Multicriteria analysis**
   Quantitative + qualitative

The **complexity of the analysis** must reflect the complexity of the regulatory problem.

# Operational tool: RIA form

*The guide includes a structured form to support technical teams at each stage of the analysis.*

**RIA Form — v.1.0**

| | | |
|---|---|---|
| § 1 | **Problem diagnosis** | — free text |
| § 2 | **Affected actors** | — list |
| § 3 | **Legal basis** | — references |
| § 4 | **Objectives** | — SMART |
| § 5 | **Alternatives** | — matrix |
| § 6 | **Impacts** | — cost-benefit |
| § 7 | **Public Participation** | — consultations |
| § 8 | **Implementation and evaluation** | — plan |

**Operational benefit**

It ensures **consistency, traceability, and comparability** among analyses by different teams.

The guide not only explains how to conduct an RIA — it **also offers concrete tools to apply it**.

# The self-assessment checklist

*Ten dimensions of regulatory quality — it allows review of the consistency of an RIA before decision-making.*

- ✓ 01 **Problem**
- ✓ 02 **Affected actors**
- ✓ 03 **Legal basis**
- ✓ 04 **Objectives**
- ✓ 05 **Alternatives**
- ✓ 06 **Benchmarking**
- ✓ 07 **Impacts**
- ✓ 08 **Public Participation**
- ✓ 09 **Risks**
- ✓ 10 **Implementation and monitoring**

Practical usefulness

**10**

dimensions of regulatory quality

It makes it possible to review the consistency and quality **of an RIA before decision-making**.

What it is for

A quick verification before moving to the final decision — **point by point**.

# Main findings of the guide

## 1

### RIA improves decisions

It is a tool to improve regulatory decisions, not a bureaucratic procedure.

## 2

### The problem defines the rule

The correct definition of the problem determines the quality of regulation.

## 3

### Assess the non-regulatory

Non-regulatory alternatives must be assessed before imposing new obligations.

## 4

### Proportionality

Proportionality defines the depth of the analysis to be conducted.

## 5

### Monitoring and ex post

RIA is completed only with monitoring and ex post evaluation of results.

The objective **is not to produce more regulation**.

The objective is to **produce better regulatory results** for patients, the health system, and innovation.

# Thank you


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