

**e-IFU:
Strategies to
implement as
general
practice**

8-May-2025



INTER-AMERICAN COALITION FOR

REGULATORY CONVERGENCE

MEDICAL TECHNOLOGY SECTOR



ANNIVERSARY

e-IFU Working Group

Problem Statement

Some countries in LATAM do not accept e-IFU, however, it is a trend adopted for many companies

Main Objective

Provide documents/position that support the strategies to advocate e-IFU adoption across the countries.

General activities

			2025									
	Activity	Estatus	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Oct	Nov
1	Compiling state of art	Completed										
2	Discussion position papers available	Completed										
3	Main concerns of Health Authorities	In progress										
3.1	Internet connection	Completed										
3.2	Users do not feel comfortable with e-IFU (Survey)	In progress										
	Define audience (HCPs, HC Institutions, HCP associations) and ways to contact them	Completed										
	Survey question	Completed										
	Pilot of the survey	Completed										
	Survey release	Not started										
	Data collection	Not started										
	Data analysis	Not started										
3.3	IFU printed on demand	In progress										
3.4	version control	In progress										
4	Position document to recommend e-IFU	In progress										
5	General Strategy to negotiate with Health Authorities	Not started										

Survey:

Methodology	
Audience	Health Care professionals
Scope	Argentina & Colombia
Distribution strategy	TBD: Coalition Vs Loc trade associations will distribute survey across professional associations.
Data collection	1 -2 months
Type of questions	Intended to understand what are the preferences of HCP regarding IFU (paper vs. e-IFU).

- Lay user products excluded from survey.
- Survey already validated by HCPs into the companies.



THANK YOU