

# The 2<sup>nd</sup> Brazil – Japan Seminar on Regulations of Pharmaceuticals and Medical Devices

## Enhancing Efficiency

Tokyo, Japan – September 2015



Agência Nacional  
de Vigilância Sanitária

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[www.anvisa.gov.br](http://www.anvisa.gov.br)

# The Mission of Anvisa:

**“To protect and promote public health and to intervene in risks...”**



# Anvisa:

- ✓ **A Federal Public Organization;**
- ✓ **Stablished by Congress law;**
- ✓ **Ruled by a Collegiate Board of Directors (5).**



# FIELDS UNDER ANVISA'S REGULATIONS



*Foods*



*Cosmetics*



*Sanitizing  
Products*



*Tobacco*



*Pesticides*



*Health Related  
Services*



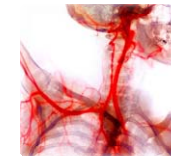
*Medicines*



*Medical devices*



*Official Laboratories*



*Blood, Tissues and  
organs*



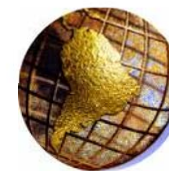
*Pharmacovigilance*



*Advertising*



*Ports, airports  
and borders*



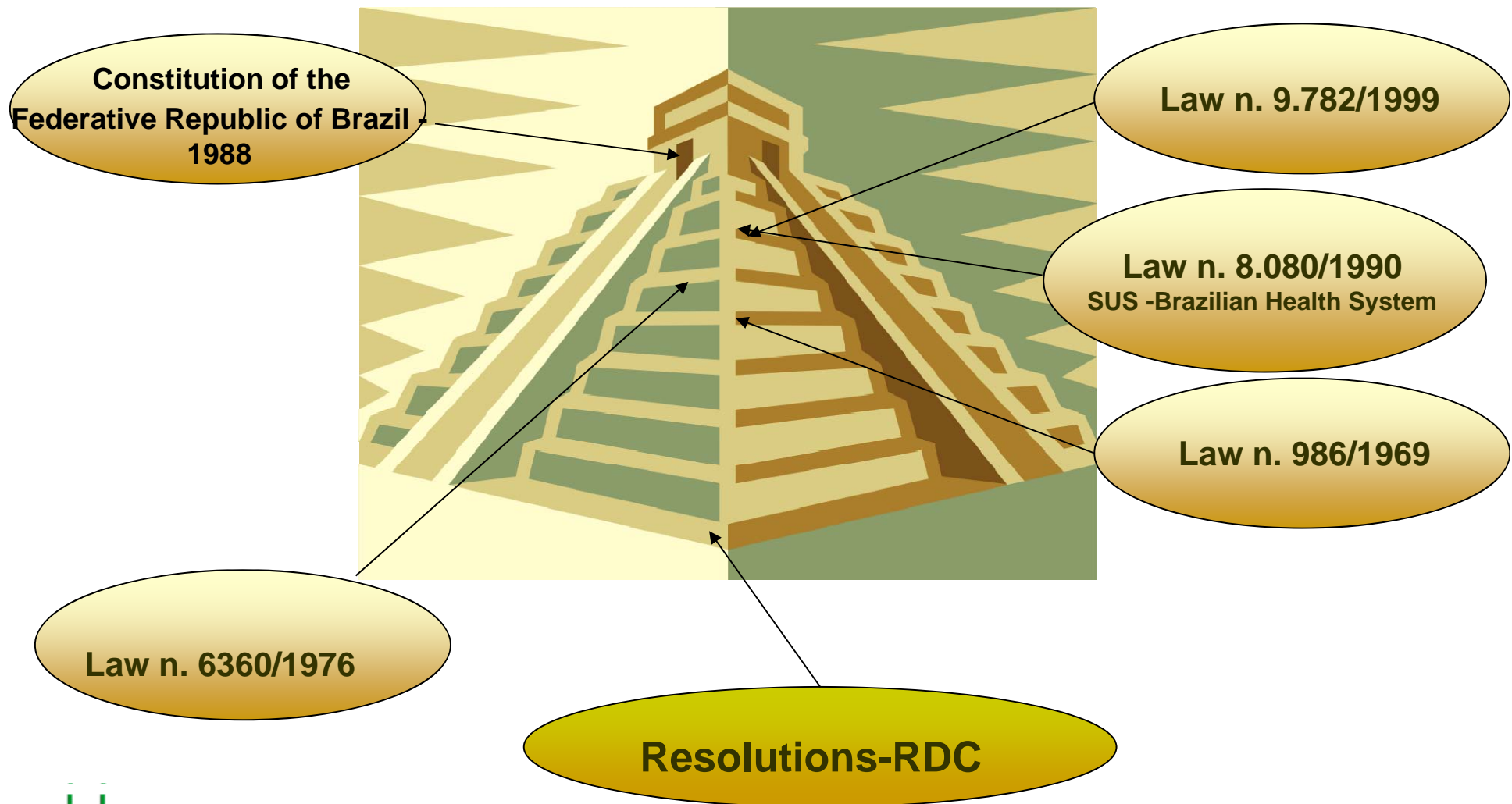
*International affairs*



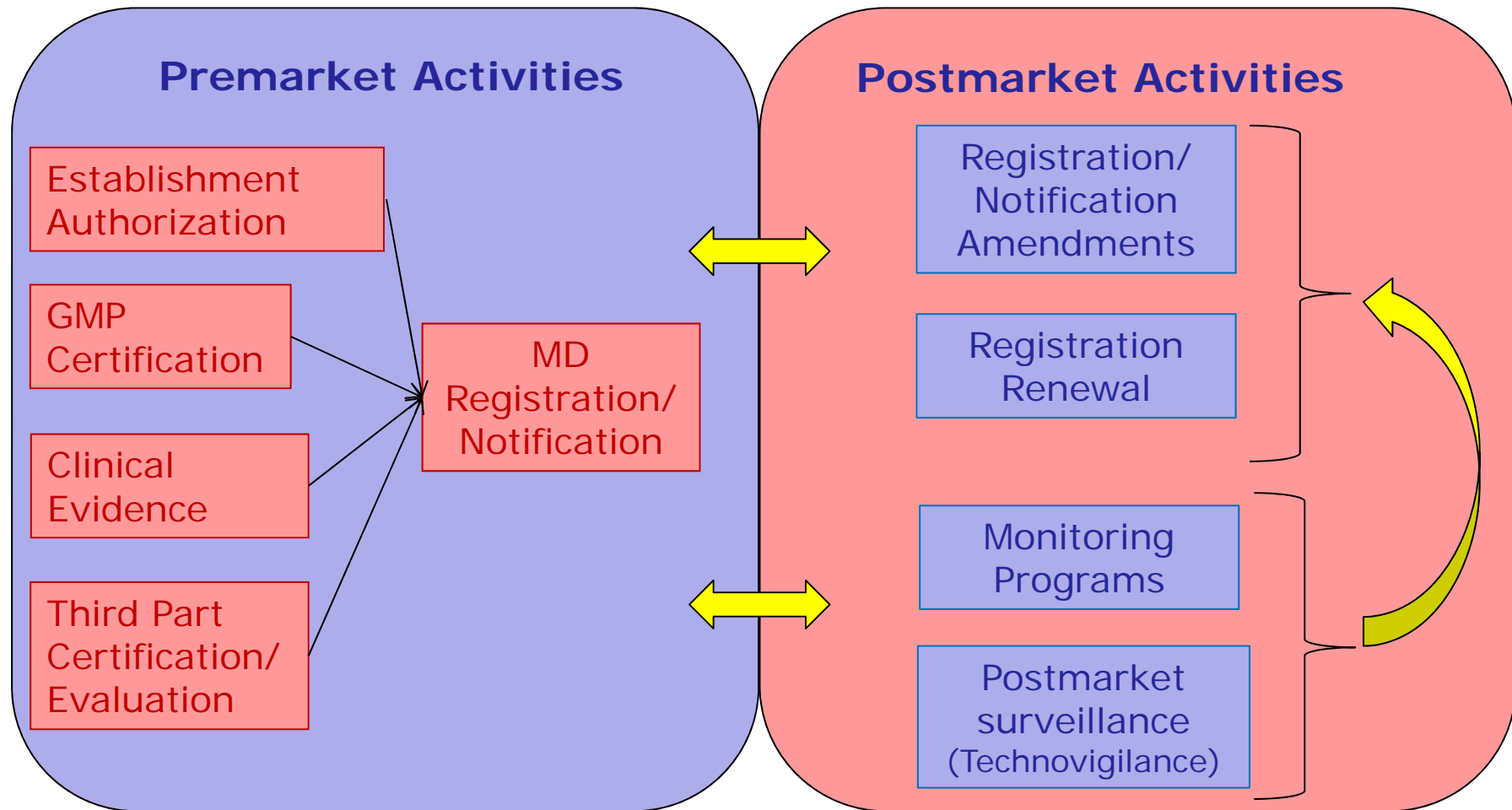
*Coordination of the  
National Health  
Surveillance System*



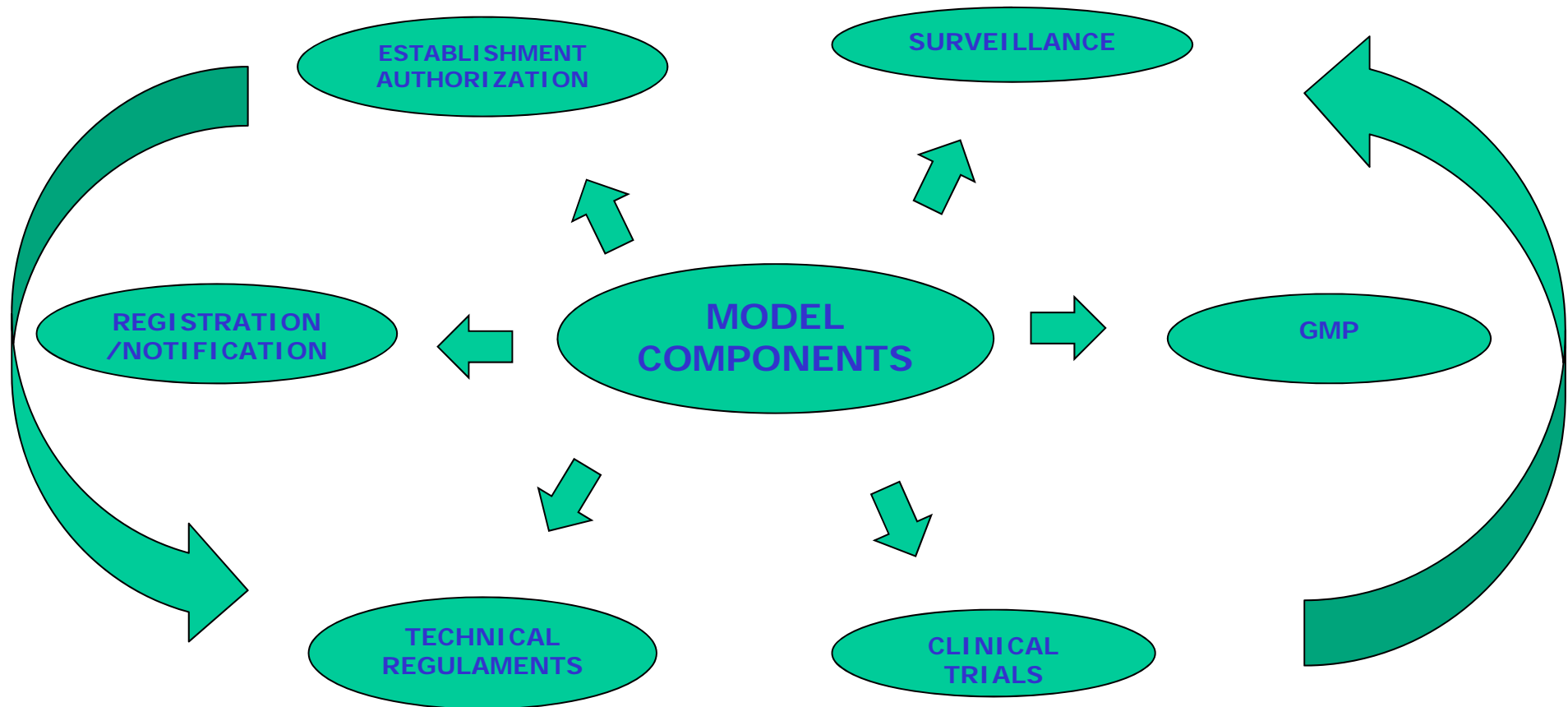
# LEGAL FRAMEWORK



# Overview of the Regulatory Scheme



# QUALITY ASSURANCE MODEL FOR MEDICAL DEVICES



# Two types of pre-market submission

- based on risk-

✓ Notification      ✓ Registration

**Risk classes  
I and II**

(Glucometer; surgical gloves;  
wheelchairs; syringes;  
infusion sets)

**Risk classes  
III and IV**

(hip implants; stents; X-ray  
equipments)





# Requirements

## ✓ Notification

- Submission
- Number by Anvisa
- Simple form
- 3<sup>rd</sup> part certification\*

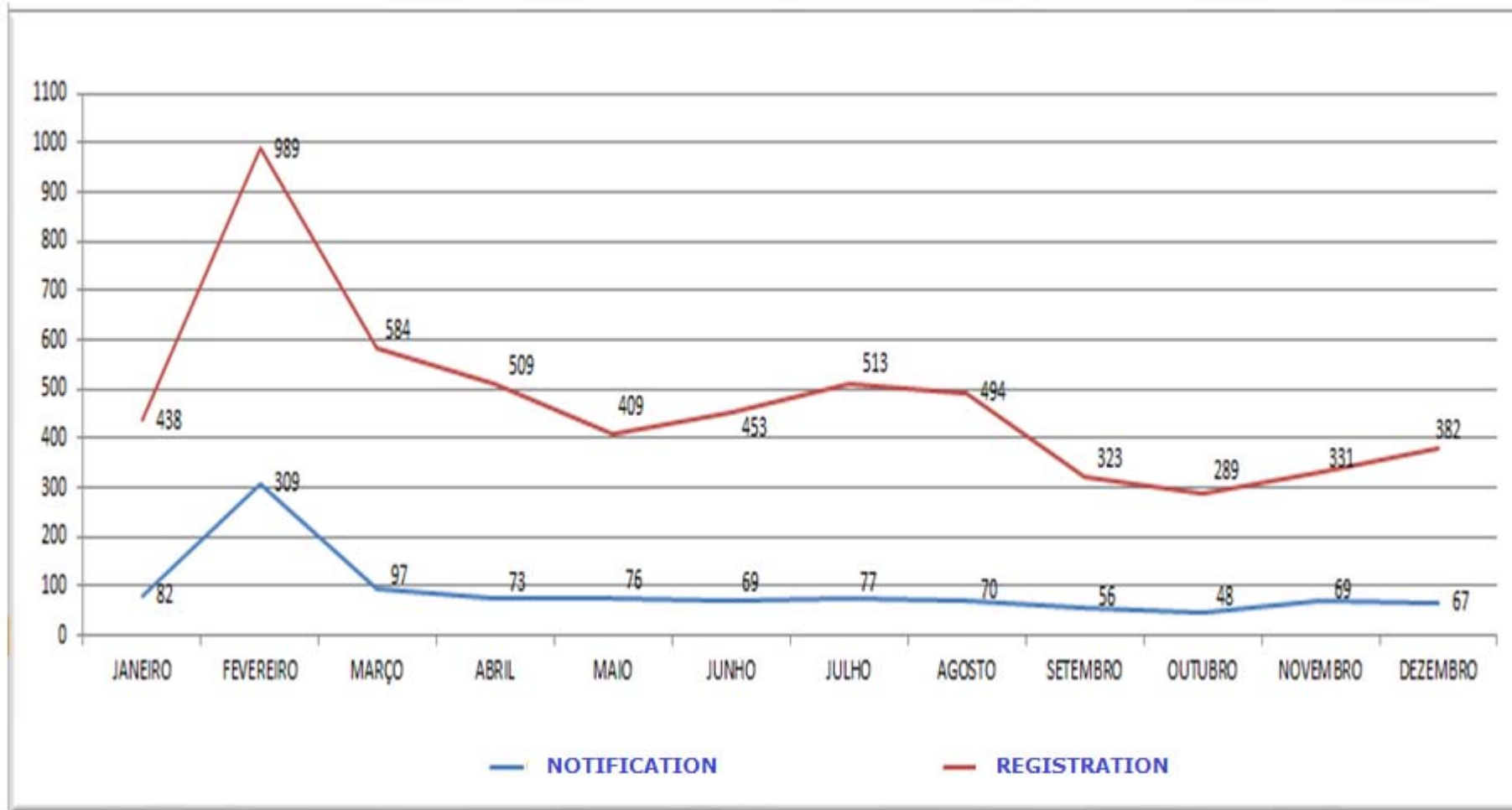
\*Gloves; needles; seringes; equipo.

## ✓ Registration

- Submission
- Number by Anvisa
- Simple form
- 3<sup>rd</sup> part certification
- Inspection by Anvisa
- Technical report
- Essay
- New requirements to clarify any points
- Scientific evidence
- Clinical trial



# Deadlines for registration and notification



# Approved and rejected submissions-2014

AREAS	GEMAT				GQUIP				GEVIT			
	DEF	%	INDEF	%	DEF	%	INDEF	%	DEF	%	INDEF	%
REGISTRATION	711	67%	352	33%	533	96%	23	4%	995	95%	56	5%
NOTIFICATION	3725	85%	632	15%	1176	86%	191	14%	188	94%	11	6%
TOTAL GGTPS	4436	88%	984	12%	1709	92%	214	8%	1183	95%	67	5%



# Main challenges

- Increasing the number of technical staff;
- Meeting deadlines and reducing time needed to assess submissions

# Thank you!

Cleber Ferreira dos Santos  
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GGTPS



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