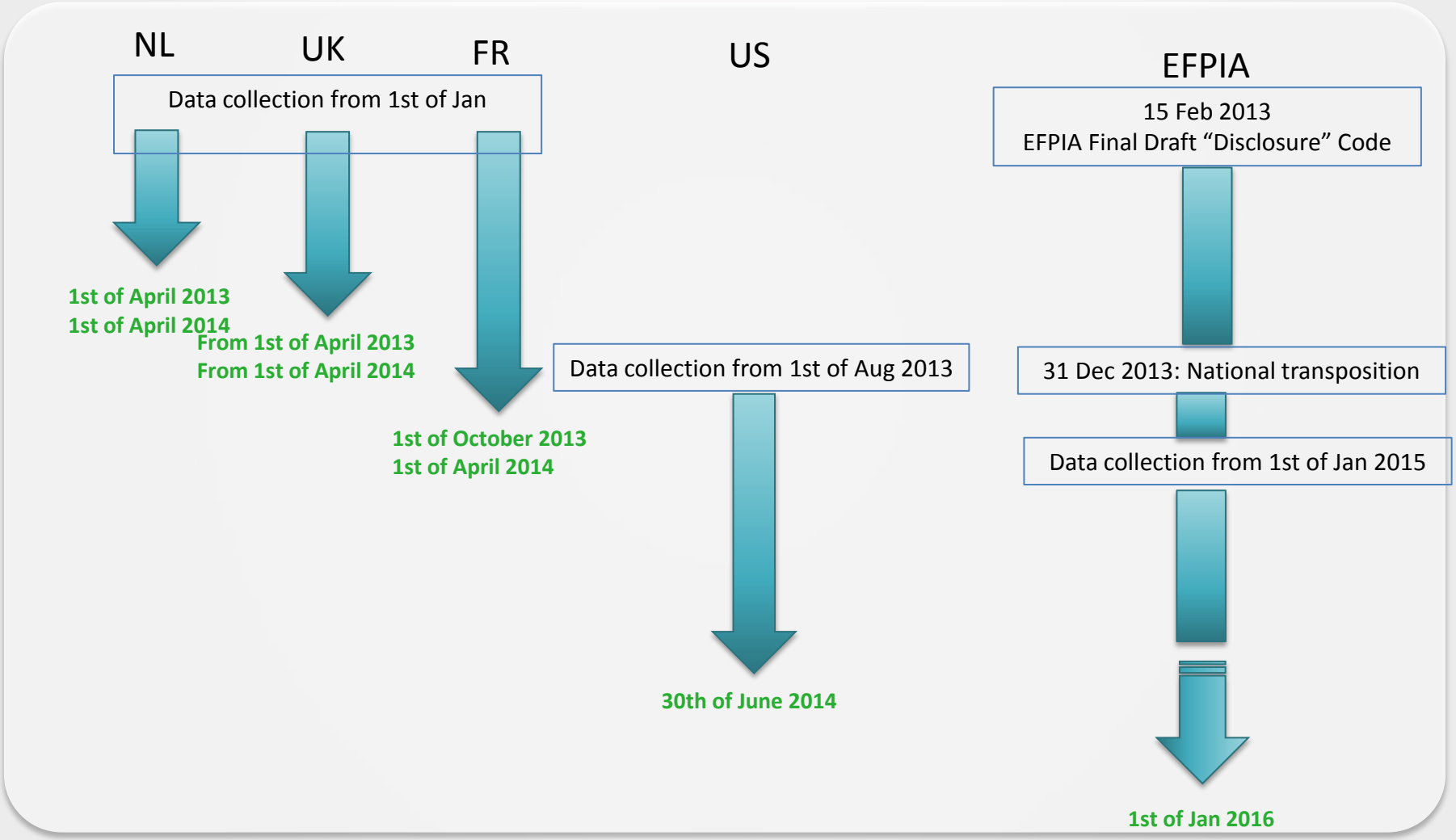
EFPIA disclosure

How to implement a global solution which respects local regulation

Be ready for 1st of January 2016

Disclosures roadmap



International disclosure

- The multi-country challenge
  - Local languages
  - Local currencies
  - Local alphabet!
  - Ex: EFPIA in Europe
    - >15 currencies, 3 alphabets, >30 languages
  - Laws vs code of conduct
  - Data privacy and consent issues
  - Different Fair Market Values to comply with

Process to manage HCPs and HCOs relationships

	Pre event process	Post event process	Aggregation	Continuous disclosure	Periodic disclosure
			✓		June Federal website
efpia	*Depend on each country*		✓		
	CPD submission	*CPD submission*	✓		3 months after end of fiscal year one website??
	Submission for advice	Notification	✓	For contracts (Possible for hospitality)	Twice a year on official website (Pharma & MD)
			By Pharma and HCPs		April official website
	Notification to the AIFA	Obligation to keep attendees' consent	✓		?
	Submission to MDEON		✓		?

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Potential differences between EFPIA and national requirements

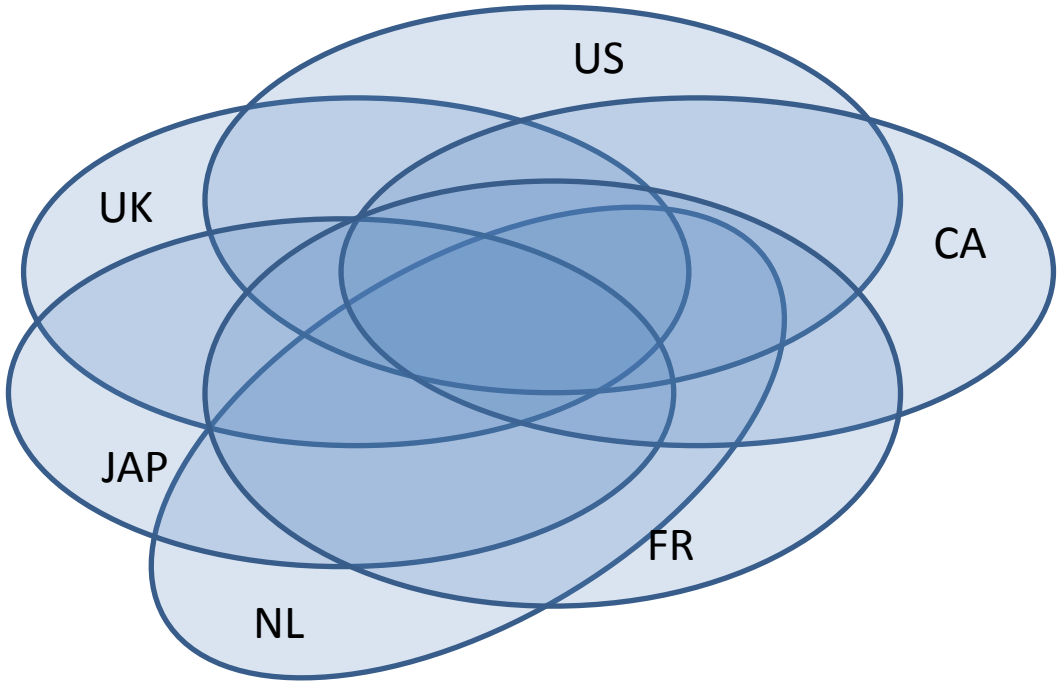
EFPIA (Q&A)	Country level
Pharma activities concerned : POM (n°6)	Can be extended to all Pharma activities, MD and cosmetic
'"each code will include the list of professional designations" (n°24)	HCP definition not the same in each country
HCO definition (n°27)	Teaching hospitals, foundations, ….
Aggregate disclosure for some ToV (n°20)	Full nominative disclosure can be required
HCP consent required	No consent needed if stated in the law
HCO consent required where applicable	HCO's consent is required in some countries
"Disclosures shall be made on an annual Basis … within 6 months"	Can be 2/year or all along the year
Platform of disclosure	Defined by each country
"information disclosed shall be required to remain in the public domain for a minimum of 3 Years"	Can vary according to national laws
"maintain the relevant records of the disclosures for a minimum of 5 years"	Can vary according to national laws

How to manage next years?

- 2 challenges
  - The roll-out phase => 33 countries within 1 year!
  - The pace of EFPIA code implementation at national level
- « Where a national disclosure is not in place, the EFPIA template must be used »
  - Which countries will implement the EFPIA disclosure template ?
  - Which countries will design their own disclosure report?
- How to address uncertainty during the software implementation phase?
  - Will all the national transpositions be achieved in 2014? in 2015?... in 2016?
  - How to manage unavoidable changes occurring the first year of disclosure (e.g. French disclosure)?

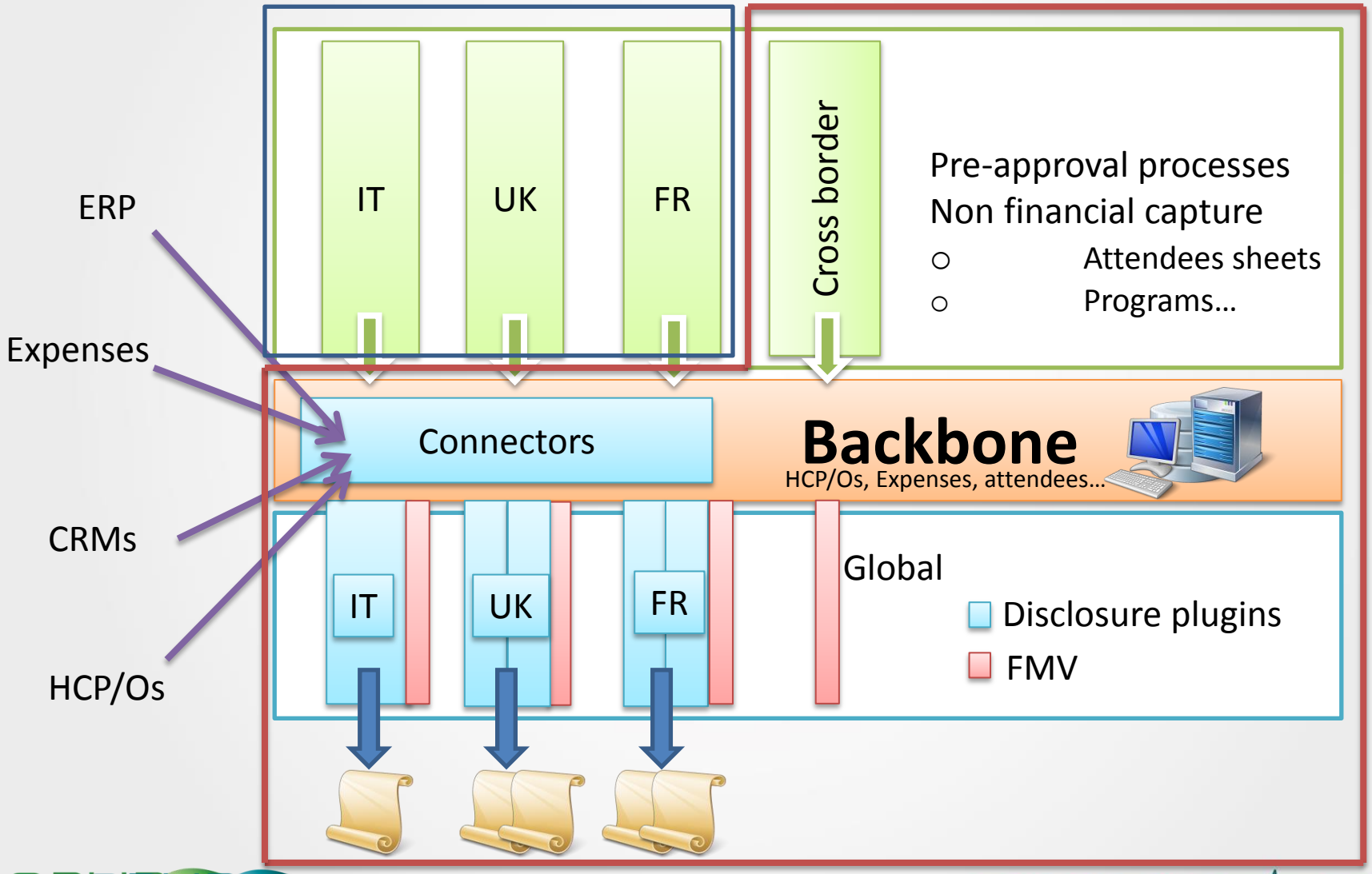
The international disclosure dilemma

The worldwide disclosure picture



- Level of details
- Countinuous vs periodically
- Local IT format
- Local language
- …

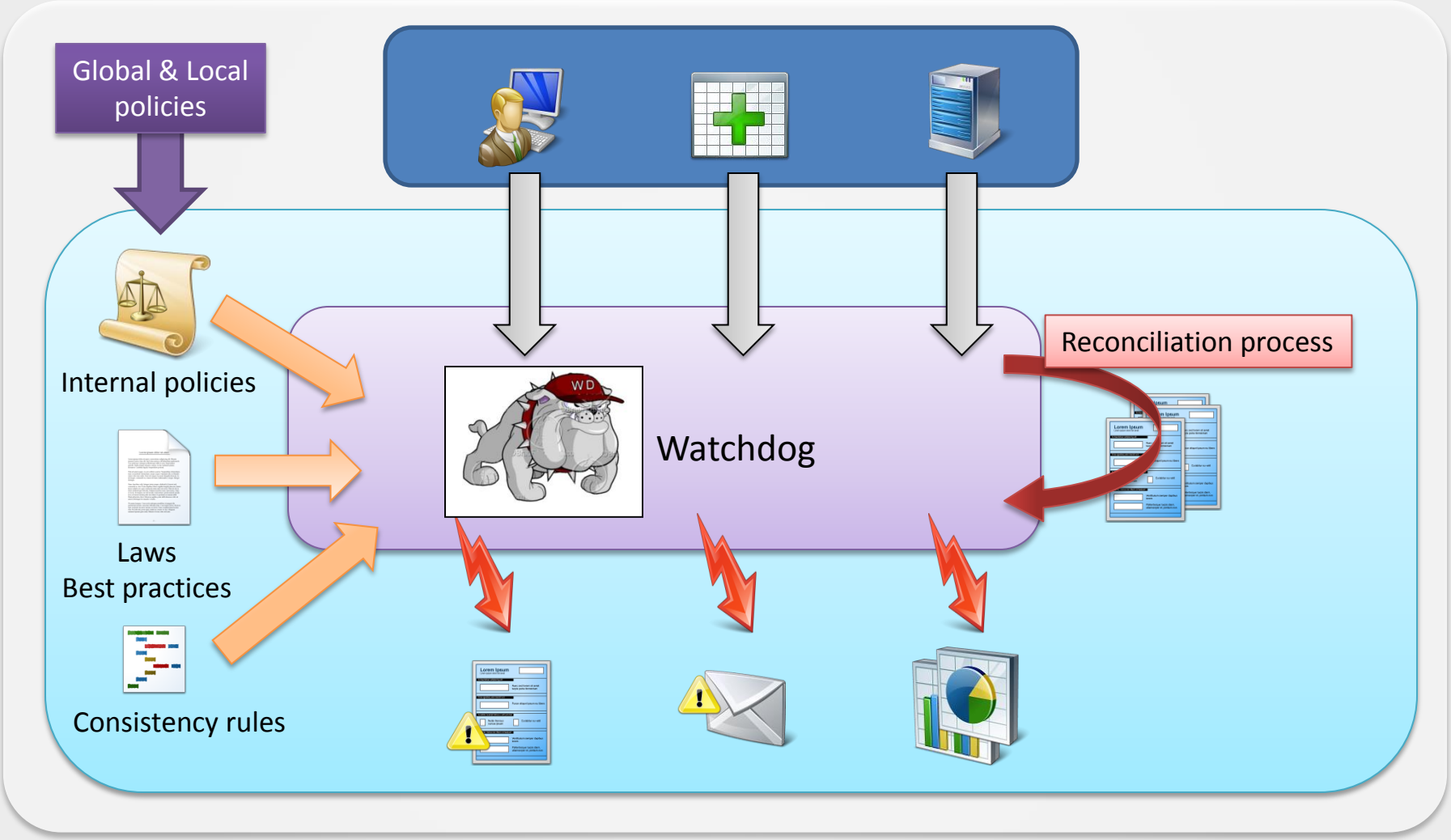
NAYA Disclosure Architecture



Manage cross borders events

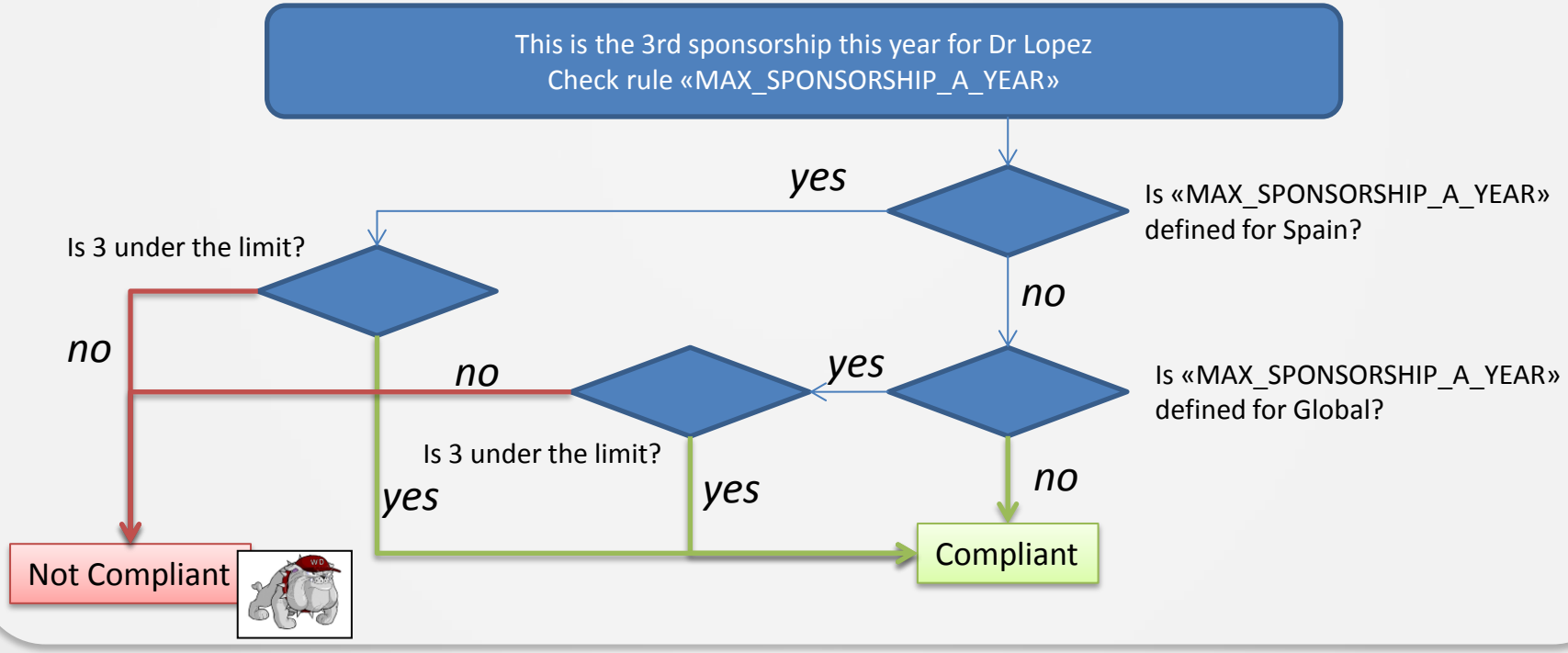
- Pre-approval process
- Tightly connected to disclosure plugins & backbone
- HQ operations & cross border affiliate operations
- Approval by host country, HQ, participant countries
- Complete operation repository
  - Letters, speaker contracts, submission to authorities…
- Can be used for local operations
- Can be upgraded to local approval processes

NAYA Watchdog & FMV

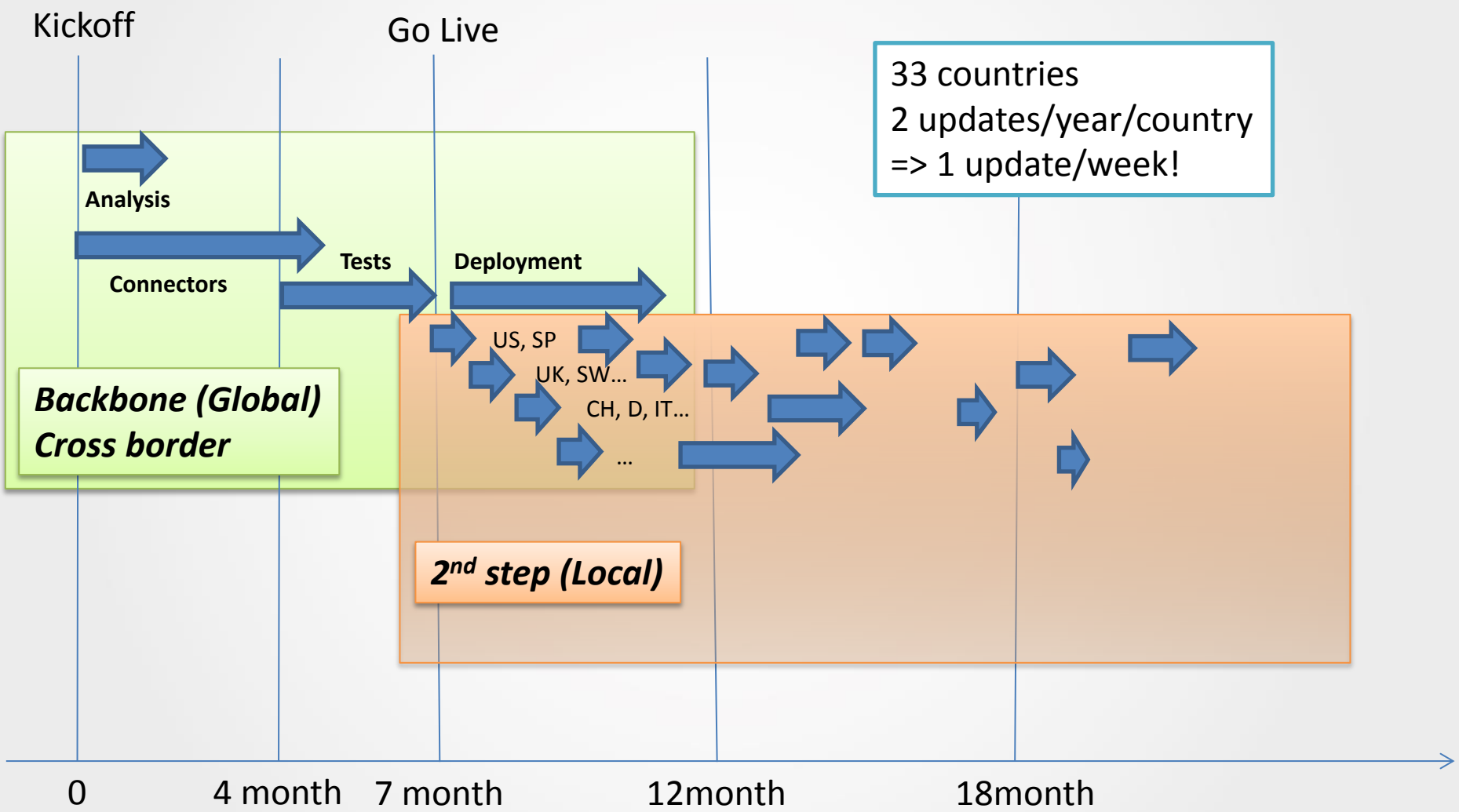


FMV Global vs local rules

- Rule names
  - MAX_MEAL_AMOUNT, MAX_SPONSORSHIP_A_YEAR…
- Algorithm
  - is the sponsorship for Dr Lopez in Spain compliant?



Roadmap


Kickoff
Go Live
33 countries
2 updates/year/country
=> 1 update/week!
Analysis
Connectors
Tests
Deployment
US, SP
UK, SW…
CH, D, IT…
…
Backbone (Global)
Cross border
2nd step (Local)
0
4 month
7 month
12month
18month

Next step….

Identify practical issues to take into account when implementing a transparency process

=> workshop « **How to implement transparency procedures/Disclosure specifications”** at 5 pm

Thank You

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