Joint IMDRF/Industry Workshop on Reliance

Pre-market reliance – the EU framework

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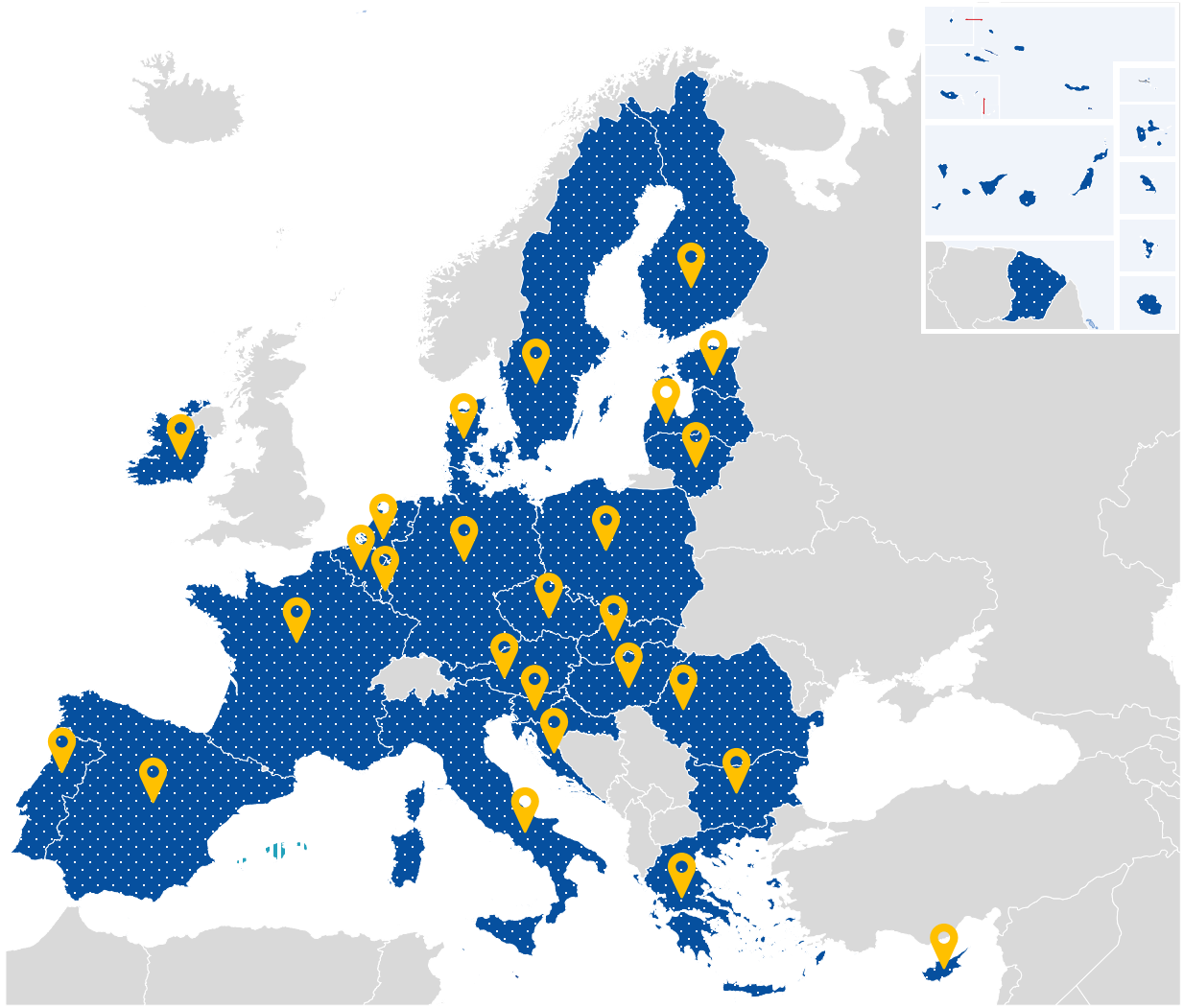
IMDRF International Medical Device Regulators Forum

Agenda

1. **EU's regulatory framework for medical devices**
2. **Overview of the EU’s pre-market reliance system**
   - Reliance in clinical investigations and performance studies
   - Reliance on standards
   - Reliance on notified bodies and designations
   - Reliance in the form of Derogations
3. **Reliance beyond the EU**
4. **Benefits of reliance and EUDAMED as a source of trust and transparency**

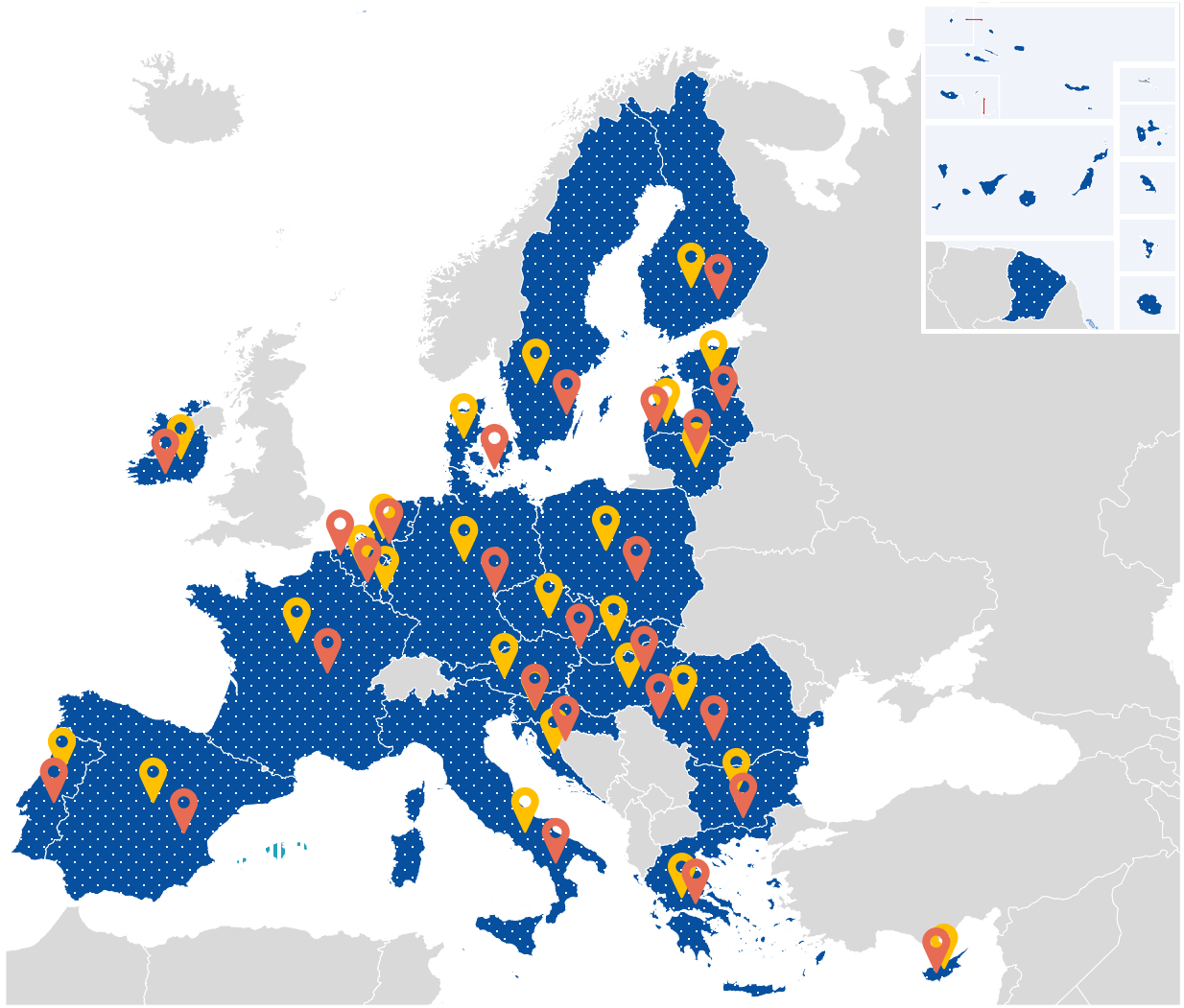
The EU 27 Member State Competent Authorities for Medical Devices



National competent authorities

European Commission

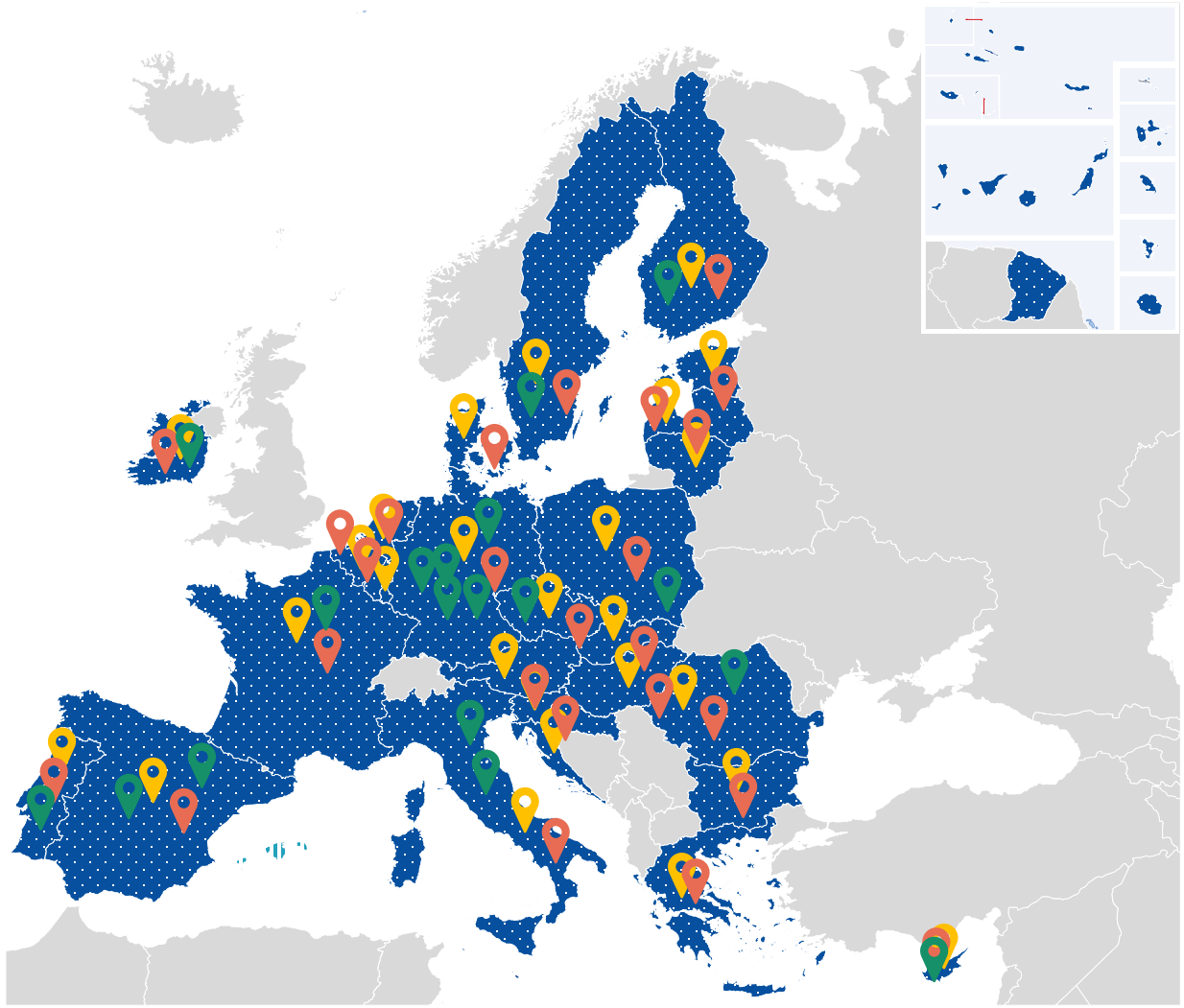
The EU 27 Member State Competent Authorities + Designating Authorities for Medical Devices



National Competent Authorities Designating Authorities

European Commission

The EU 27 Member State Competent Authorities for Medical Devices



National Competent Authorities Designating Authorities Notified Bodies

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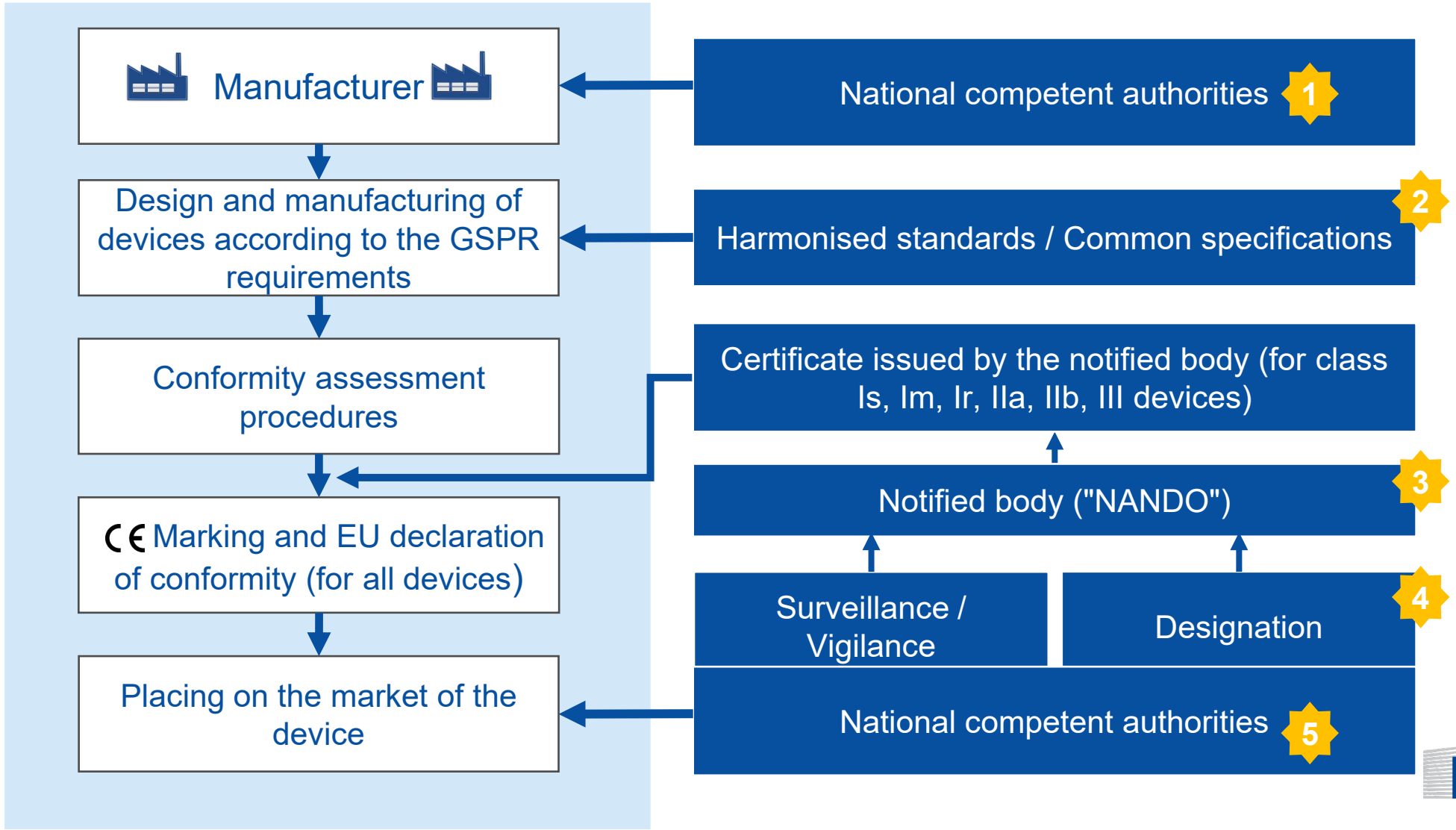
Overview of the EU's pre-market reliance



European Commission

Coordinated assessments on clinical investigations and performance studies

- Coordination when clinical investigations are conducted in more than one Member State: **1 application → 1 review**

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Harmonised Standards

- Importance of harmonized standards in demonstrating compliance with EU MDR/IVDR requirements
- While not mandatory, compliance with harmonised standards provides manufacturers with a ‘presumption of conformity’, facilitating the review of notified bodies during the conformity assessment procedures.
- Standards developed internationally are further developed at European level by European Standardisation Organisations and followed by an assessment against the MDR/IVDR by specialists and the European Commission.
- A positive assessment leads to a publication in the EU’s Official Journal

NB 2265	3EC International a.s.	Slovakia
NB 2797	BSI Group The Netherlands B.V.	Netherlands
NB 1370	BUREAU VERITAS ITALIA S.P.A.	Italy
NB 0633	Berlin Cert Prüf- und Zertifizierstelle für Medizinprodukte GmbH	Germany
NB 2409	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.	Hungary
NB 0318	CENTRO NACIONAL DE CERTIFICACION DE PRODUCTOS SANITARIOS	Spain
NB 0546	CERTIQUALITY S.r.l.	Italy
NB 0344	DEKRA Certification B.V.	Netherlands
NB 0124	DEKRA Certification GmbH	Germany
NB 0482	DNV MEDCERT GmbH	Germany
NB 2460	DNV Product Assurance AS	Norway
NB 0297	DQS Medizinprodukte GmbH	Germany

3 Notified Bodies

- Notified Bodies are designated by national authorities and notified to the Commission. The Commission assigns a four-digit identification number to each notified body (NB xxxx).
- Notified body involvement is mandated for all devices class II a and above, certain class I & Class B and above.
- Compliance of devices has to be verified by a designated notified body.
- Currently, 43 MDs, and 12 IVDs.

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Forming a Joint Assessment Team (JAT)

Member States

- ✓ Nominate experts

Commission

- ✓ Selects experts
- ✓ Schedules
- ✓ Coordinates activities

MDCG

- ✓ Endorses the appointment of the JAT

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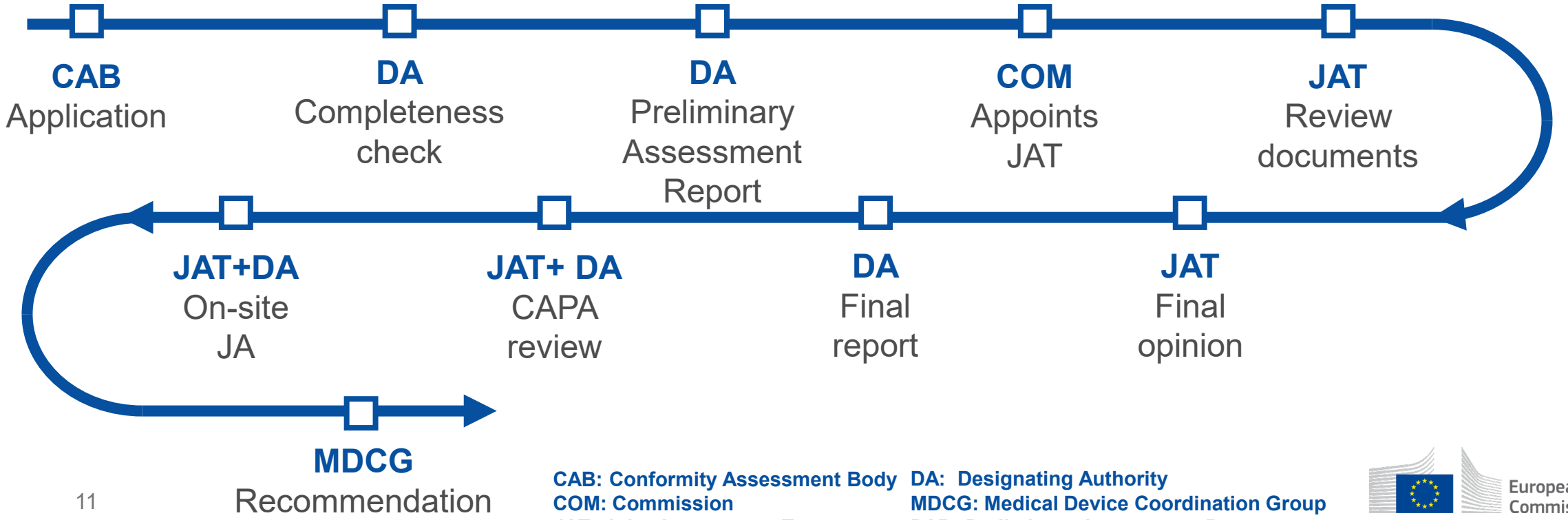
Joint assessment objectives & process

- **Initial assessment:** determine if the CAB fulfills the criteria for designation & provide a recommendation for designation
- **Re-assessment:** determine if the NB continues to fulfill criteria & provide a recommendation that the NB continues to satisfy the requirements



CAB: Conformity Assessment Body
COM: Commission
JAT: Joint Assessment Team
DA: Designating Authority
MDCG: Medical Device Coordination Group
PAR: Preliminary Assessment Report

European Commission

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Derogations

- MS coordination where derogation request affects 1+ MS
- Common criteria for assessing requests + conditions applied
- Harmonized & centralised reporting of derogations granted
- Coordination between Member States on similar requests received possible
- 1 EU wide derogation issues so far

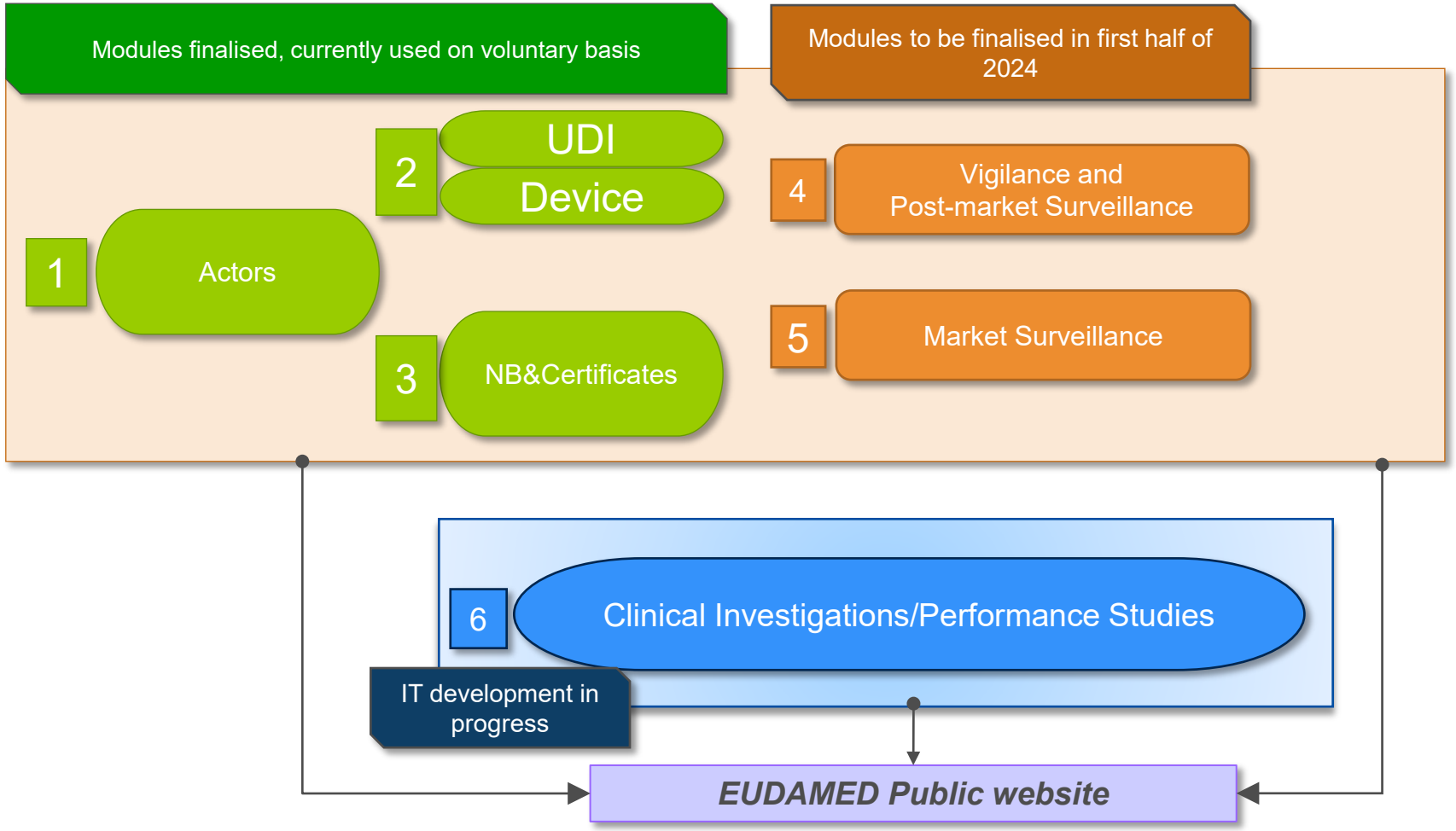
EEA,CUA, MRAs, unilateral recognition

- **European Economic Area:** non-EU member states: Liechtenstein, Norway and Iceland
- **Customs-Union Agreement:** Turkey = continuation of customs union for MDs & IVDs
    - Implications – no ARs, full integration into EU MD market - https://health.ec.europa.eu/latest-updates/notice-stakeholders-eu-turkiye-customs-union-agreement-field-medical-devices-2022-04-13_en
- **Mutual Recognition Agreements:** history of MRAs with multiple global partners (CH, AUS, NZ etc.)
- **Unilateral recognition:** UK, CH, EU candidate countries (Albania, Bosnia and Herzegovina, Georgia, Moldova, Montenegro, North Macedonia, Serbia, and Ukraine)*
- **Other forms of recognition: + 111 countries** accept EU certificates to varying degrees in their national assessments & registrations

European Commission

* EU candidate countries are currently in the process of aligning national laws to EU MDR/IVDR

EUDAMED



https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/eudamed_en

European Commission

Benefits

Greater harmonisation!

- Regulation (directly applicable) vs Directive (needs to be transposed)
- Singular registration obligations across the EU
- Clearer obligations for various economic operators
- Greater cooperation between Member States (Medical Device Coordination Group), more clarity and harmonized requirements for notified bodies
- Streamlined processes and resource saving reliance mechanisms between national authorities
- Greater cooperation between notified bodies (coordination group)
- More transparency to international counterparts on decisions-taken and public availability of relevant documents

Thank you!

Questions?

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