



# Status of Notified Bodies designated under IVDR

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FIMEA Webinar

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European  
Commission

# Content

- Introduction to DG SANTÉ of the European Commission
- SANTÉ F and its role in medical devices
- Designation of Notified Bodies & the joint assessment process
- State of play of designations of notified bodies under the IVDR



# Directorate-General SANTE

## Health and Food Safety

- Responsible for EU policy on food safety and health and for monitoring the implementation of related laws.
- Our goal is to make Europe a healthier, safer place, where citizens can be confident that their interests are protected.
- One aim is to protect and improve public health



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# Designation of Notified Bodies

Critical role in  
the regulation  
of medical  
devices

Designated by  
a MS

Assessors from  
National &  
European  
Authorities

Scope of  
designation  
based upon  
codes

NANDO  
(database of  
NBs)

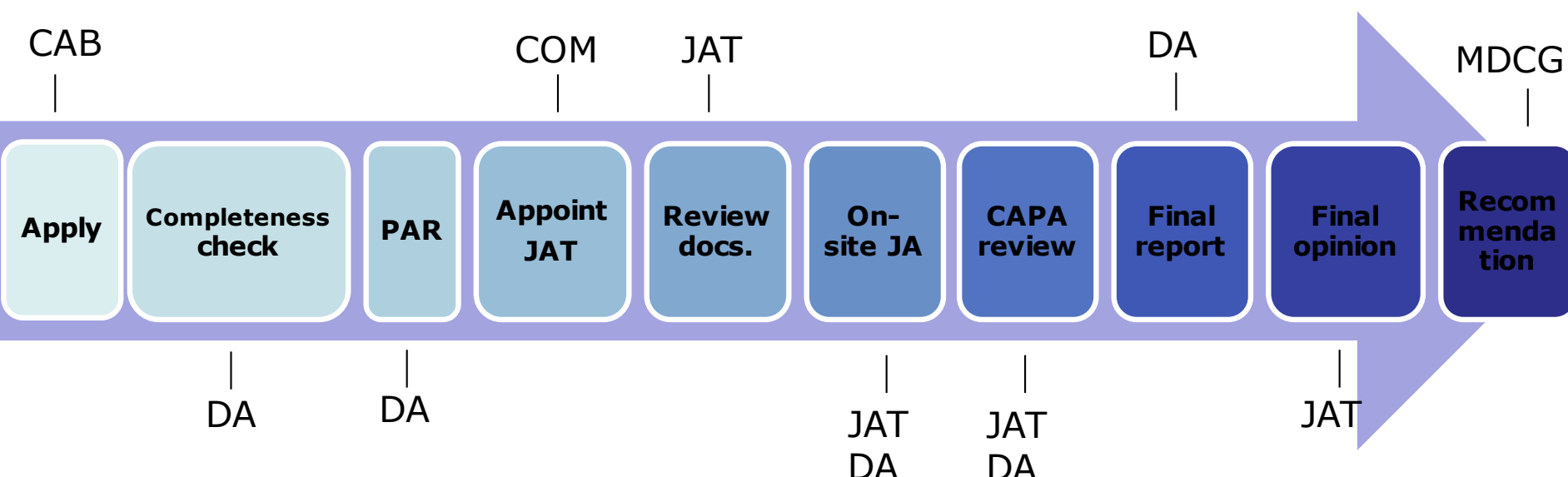
**Manufacturers  
should verify if:**

- **your NB will be / is designated under the Regulations**
- **the scope of its designation will cover all your products.**



European Commission

# Joint Assessment Process



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

# Actors in a Joint Assessment

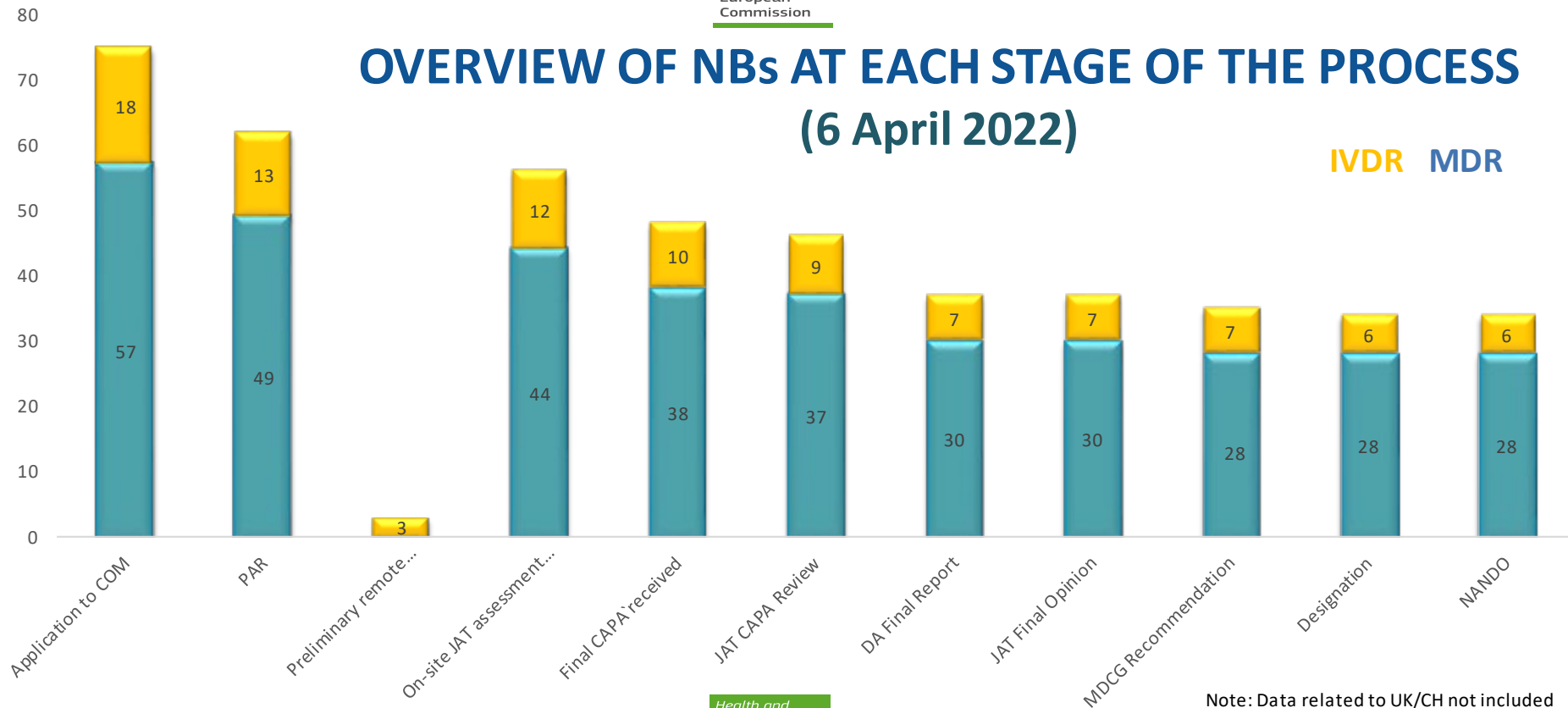
- Harmonisation
- Uniform application of legislation
- Fosters cooperation and sharing of best practice



COM: Commission  
JAT: Joint Assessment Team  
NEs: National Experts

DA: Designating Authority  
CAB: Conformity Assessment Body  
NB: Notified Body

# OVERVIEW OF NBs AT EACH STAGE OF THE PROCESS (6 April 2022)





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# INITIAL STAGES

IVDR

MDR

## APPLICATIONS

Received (total): **20**

Progressing: **18** (-UK)

Received (total): **62**

Progressing: **57** (-UK,-CH, withdrawn)



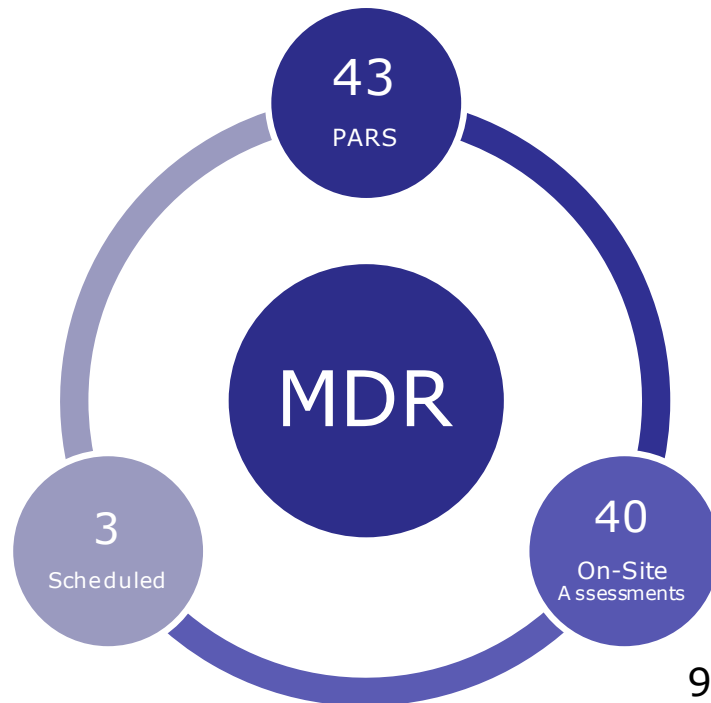
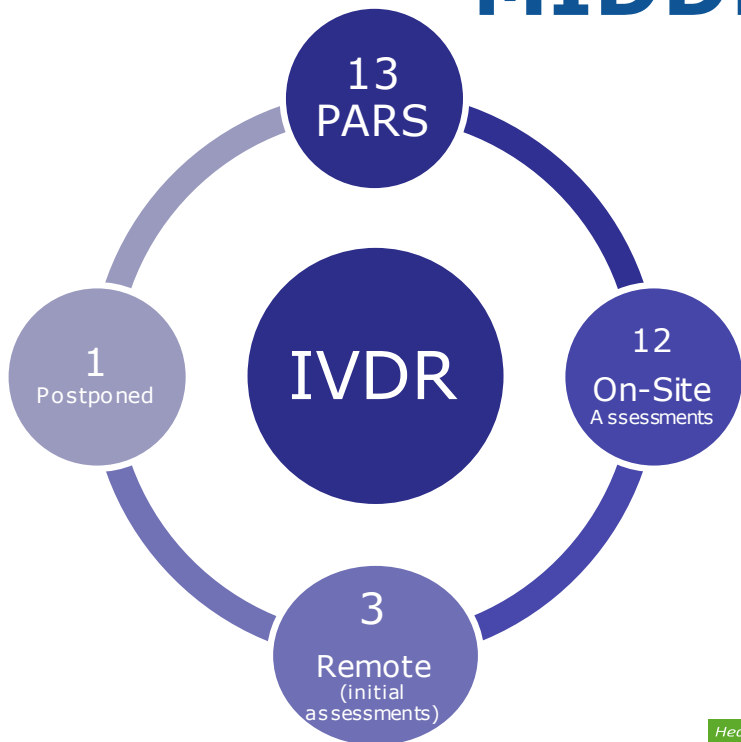
## PRELIMINARY ASSESSMENT REPORTS (PARs)

Received: **13**

Received: **49**



# MIDDLE STAGE

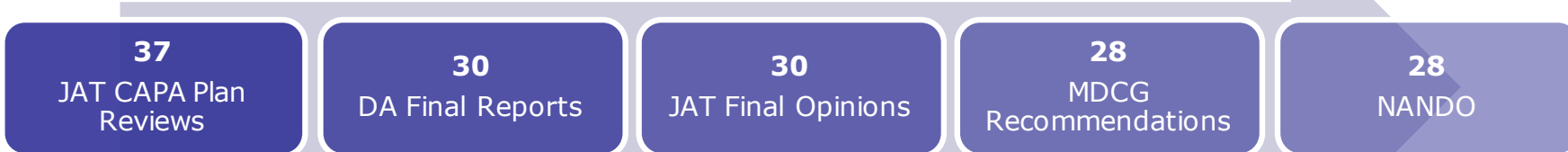


# FINAL STAGES

## IVDR:



## MDR:



# Thank you for your attention

## Any questions?