



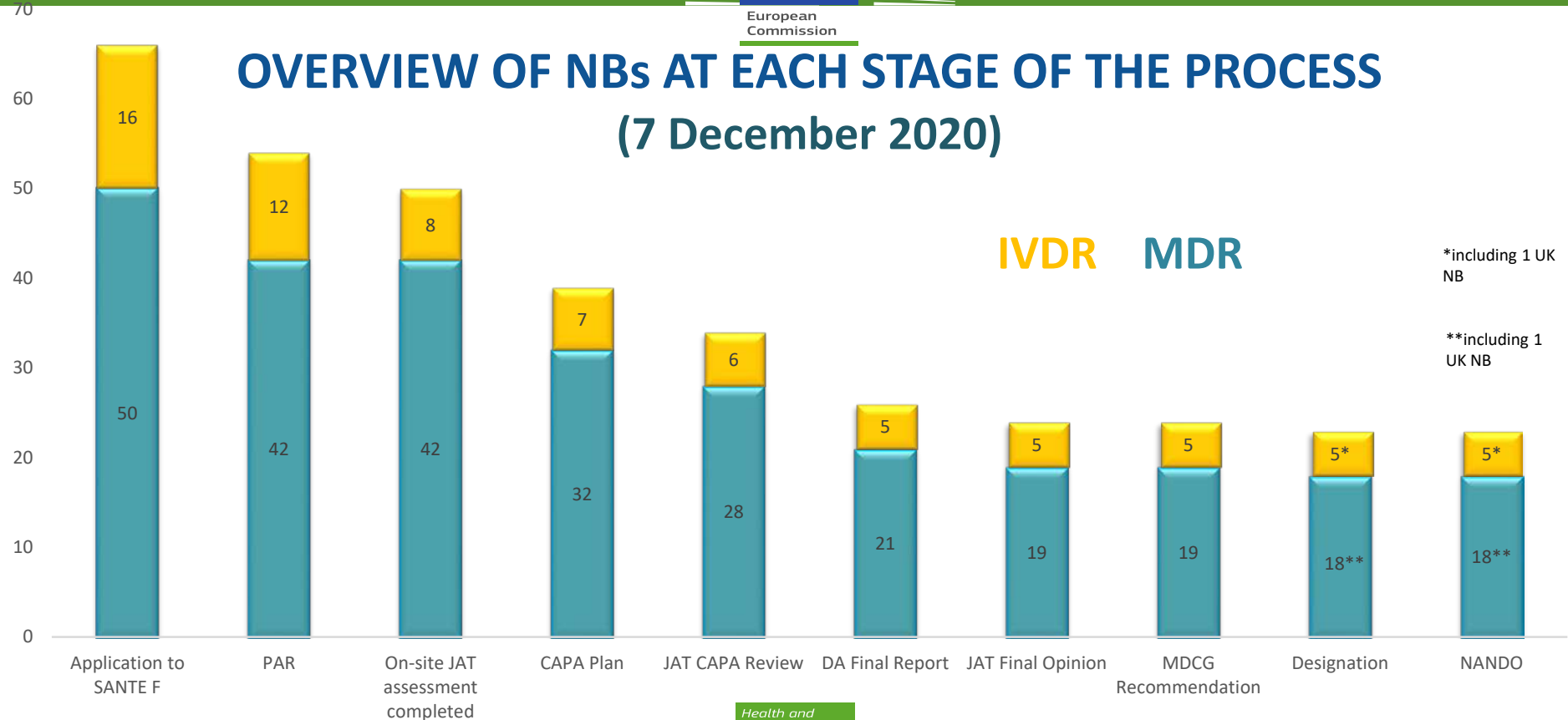
European Commission

OVERVIEW OF NBs AT EACH STAGE OF THE PROCESS (7 December 2020)

IVDR MDR

*including 1 UK NB

**including 1 UK NB



APPLICATIONS

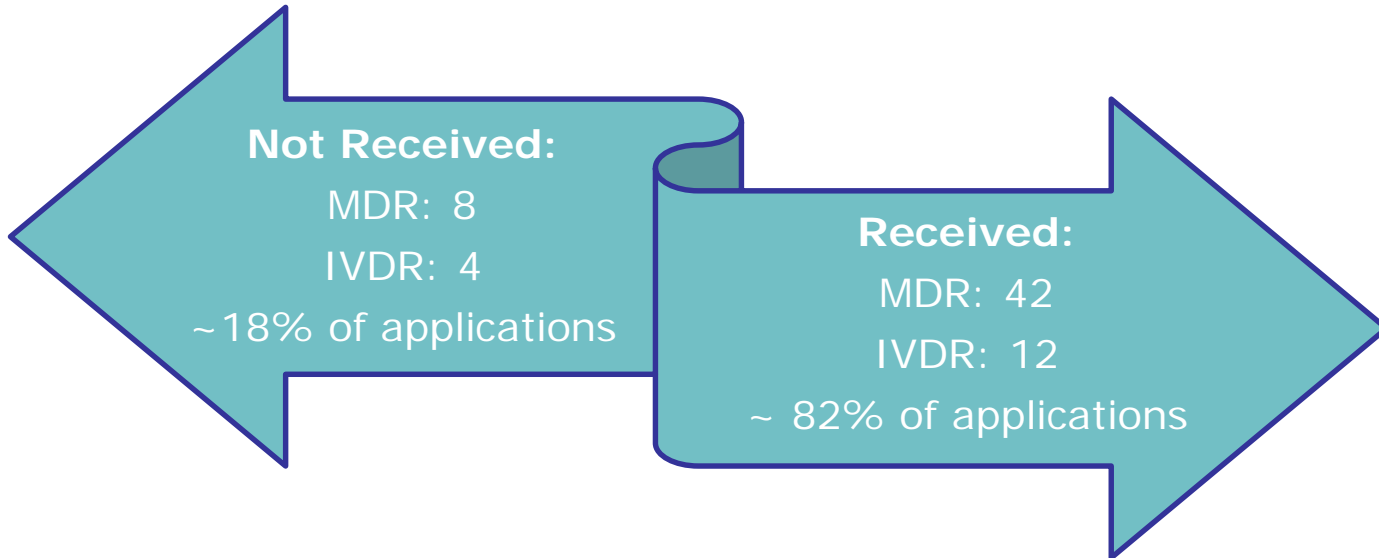
- MDR: 50 (-3 withdrawn = 47)
 - 6 new applicants (-1)
 - 44 out of 49 *current** bodies – ~90% (-2)
- IVDR: 16 (-1 withdrawn = 15)
 - 1 new applicant
 - 15 out of 21 *current** bodies – ~71% (-1)

* *Designated under the Directives, excluding bodies from Turkey*



European
Commission

PRELIMINARY ASSESSMENT REPORTS





European
Commission

FINAL STAGE

- 34 JAT CAPA plan reviews
- 7 DA final reports pending (+1 withdrawn)
- 26 DA final reports submitted
- 24 JAT final opinions issued
- 24 MDCG Recommendations
- 23 Designations notified
- 23 Designations in NANDO (18 (-1 UK) MDR +5 (-1 UK) IVDR)