

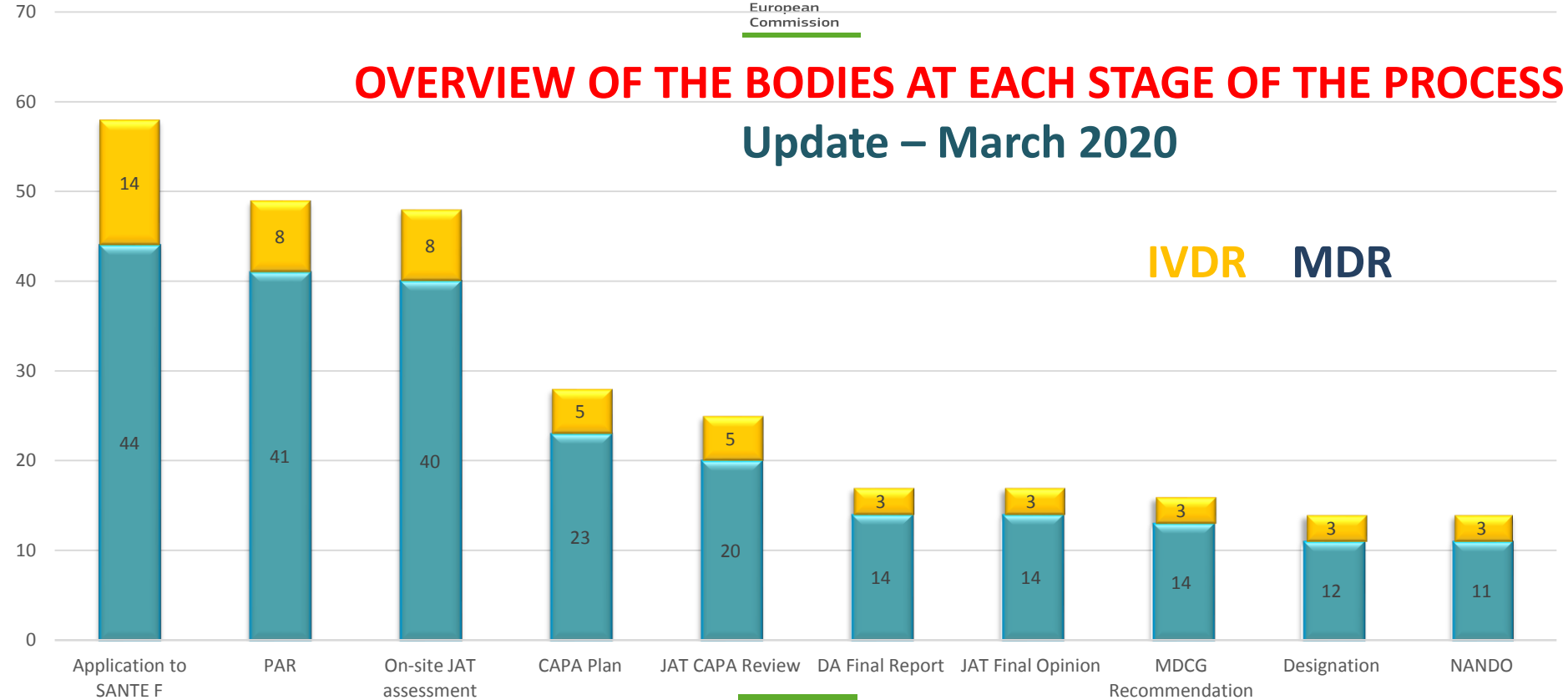


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OVERVIEW OF THE BODIES AT EACH STAGE OF THE PROCESS

Update – March 2020

IVDR MDR



58 APPLICATIONS

- MDR: 44
 - 2 new applicants (+1 withdrawn)
 - 42 out of 49 *current** bodies – 86%
- IVDR: 14
 - 1 new applicant
 - 13 out of 21 *current** bodies – 62%

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

49 PRELIMINARY ASSESSMENT REPORTS

- 41 – MDR
- 8 (+1 withdrawn) – IVDR
- **85% of applications**



ON-SITE ASSESSMENTS

		MDR	IVDR
Completed	2018	16	5
	2019	22	2
	2020	2	1
Pending		1	0



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PROCESSING OF CAPA PLANS

- 48 on-site assessments completed
- 19 CAPA plans pending
- 28 CAPA plans received (+1 withdrawn)
 - 25 JAT CAPA plan reviews issued
 - 3 JAT CAPA plan reviews pending



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FINAL STAGE

- 25 JAT CAPA plan reviews
- 8 DA final reports pending
- 17 DA final reports submitted
- 17 JAT final opinions issued
- 17 MDCG Recommendations
- 15 designations notified
- 14 designations published in NANDO