

HTA CG

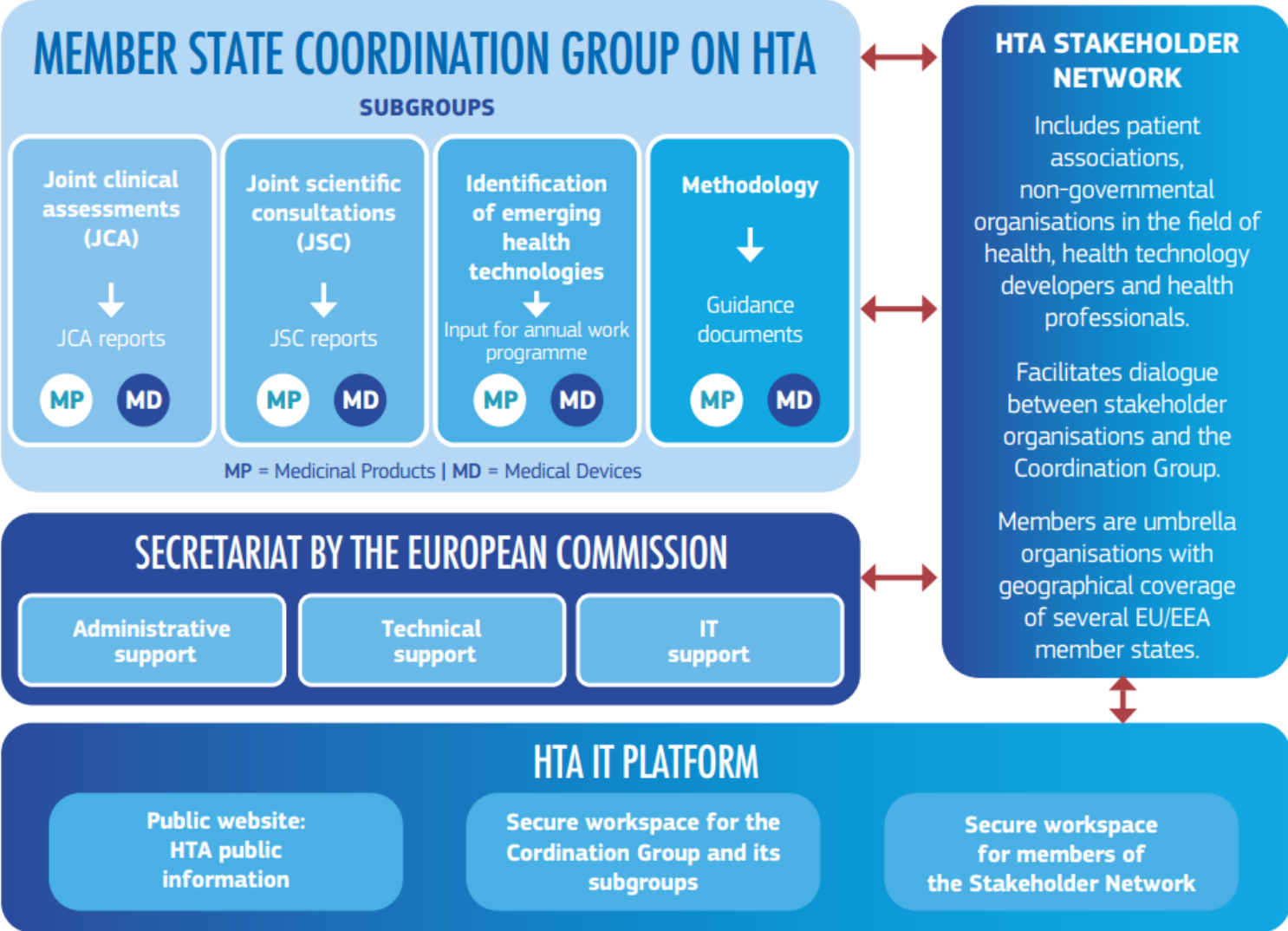
MEMBER STATE COORDINATION GROUP
ON HEALTH TECHNOLOGY ASSESSMENT



CDDF Webinar: EU HTA Regulation

Niklas Hedberg
Co-Chair HTACG
March 12th 2025

Governance



Guidance on the Joint Clinical Assessment (JCA)

HTA Regulation

https://health.ec.europa.eu/publications/regulation-eu-20212282-health-technology-assessment_en

Implementing
Regulation

https://health.ec.europa.eu/health-technology-assessment/key-documents_en?f%5B0%5D=topic+topic%3A226

Guidance documents
by the HTACG

https://health.ec.europa.eu/health-technology-assessment/key-documents_en?f%5B0%5D=topic+topic%3A227

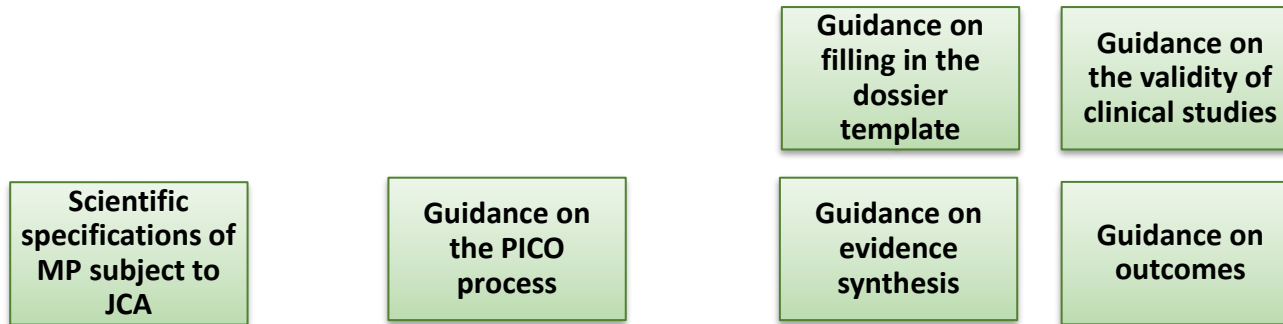
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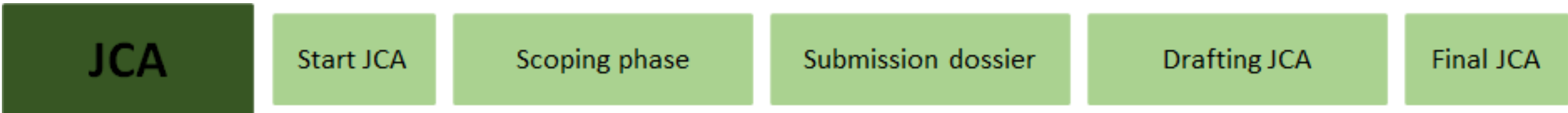
Implementing acts - status

1 st	Procedural rules for <u>JCA of medicinal products</u>	Adopted 23 May
2 nd	Procedural rules on the <u>cooperation with the EMA</u>	Adopted 18 October
3 rd	Procedural rules for the <u>management of conflicts of interest</u>	Adopted 25 October
4 th	Procedural rules for <u>JSC of medicinal products</u>	Adopted 18 December
5 th	Procedural rules for JSC of medical devices and IVD medical devices	Adopted 24 January
6 th	<i>Procedural rules for <u>JCA of medical devices and IVD medical devices</u></i>	<i>In preparation</i>

Guidance for HTDs along the process



JCA procedural guidance: process steps



IA JCA: Complete process

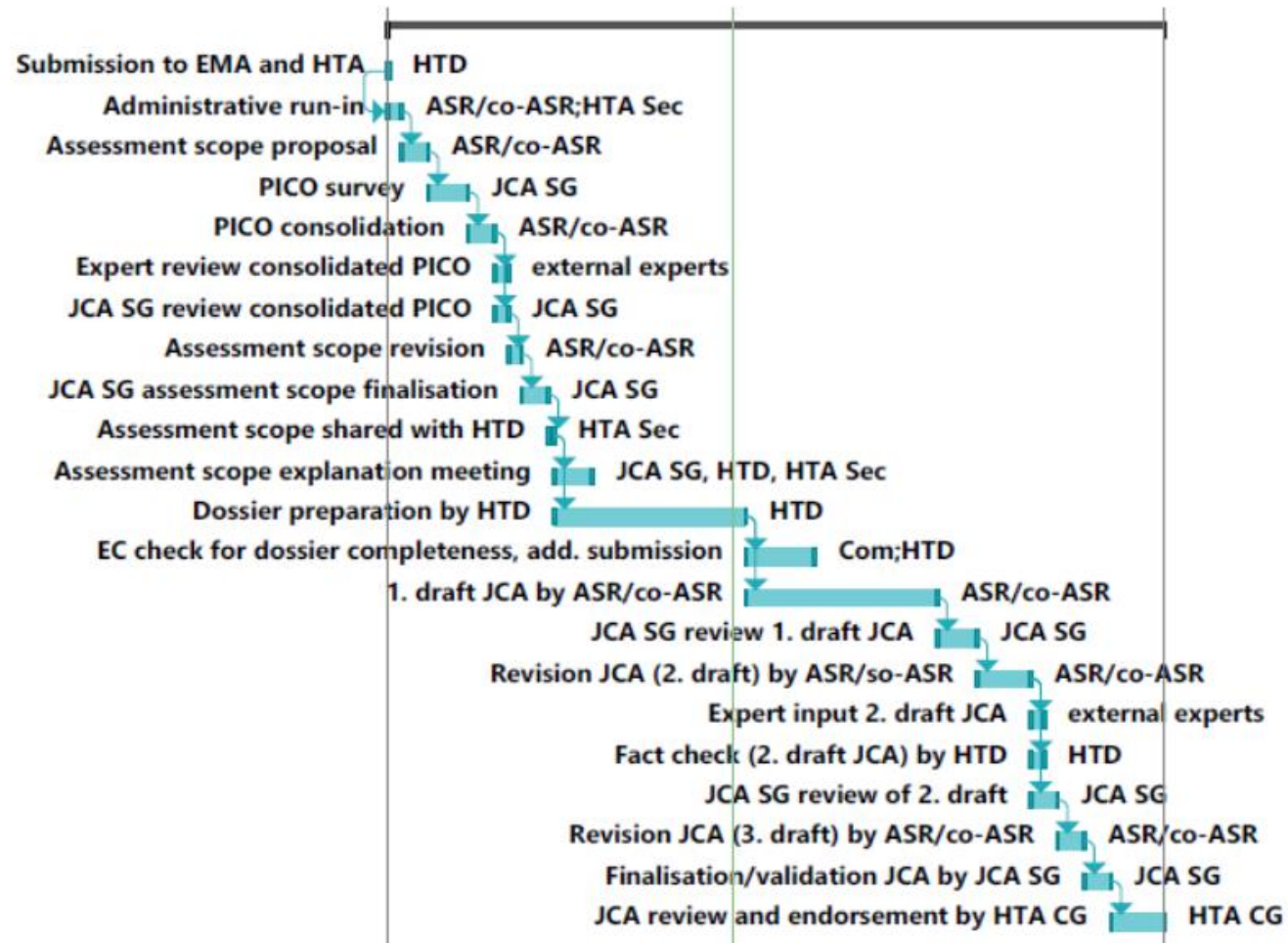
Annex to IA JCA
Dossier template

Annex to IA JCA
JCA report template



Standard procedure

JCA procdure - NCE; standard procedure	406 dys
Submission to EMA and HTA	1 dy
Administrative run-in	7 dys
Assessment scope proposal	14 dys
PICO survey	21 dys
PICO consolidation	14 dys
Expert review consolidated PICO	7 dys
JCA SG review consolidated PICO	7 dys
Assessment scope revision	7 dys
JCA SG assessment scope finalisation	14 dys
Assessment scope shared with HTD	3 dys
Assessment scope explanation meeting	20 dys
Dossier preparation by HTD	100 dys
EC check for dossier completeness, add. submission	36 dys
1. draft JCA by ASR/co-ASR	100 dys
JCA SG review 1. draft JCA	21 dys
Revision JCA (2. draft) by ASR/so-ASR	28 dys
Expert input 2. draft JCA	7 dys
Fact check (2. draft JCA) by HTD	7 dys
JCA SG review of 2. draft	14 dys
Revision JCA (3. draft) by ASR/co-ASR	14 dys
Finalisation/validation JCA by JCA SG	14 dys
JCA review and endorsement by HTA CG	28 dys





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Thank you!