Clinical Investigation Submission Under the MDR

MDR & practical challenges

National implementations

Site support

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Mandatory	As applicable
Cover letter	Risk management documentation Test reports Proof of CI Insurance Suitability of investigational sites and investigational site team IFU Suitability of investigators Recruitment procedures and advertising materials Patient information, consenting procedure, payment and compensation to participants Notified Bodies certificates Decision of other countries PMCF plan Expert panel opinion Other documents
Application form	
IB including any annexes	
CIP and CIP synopsis	
Statement of Conformity	
Example labels	
Arrangements to comply with GDPR	
GSPR	

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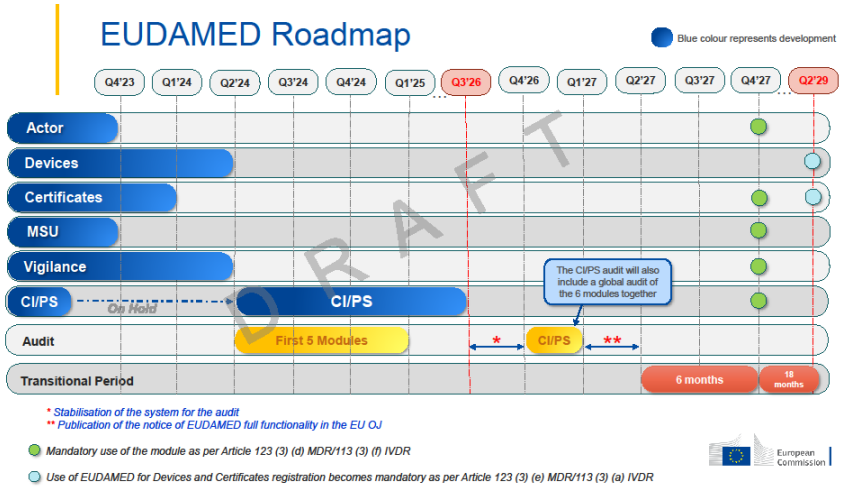

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