

## Clinical Investigation Submission Under the MDR

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MDR & practical challenges National implementations Site support



	MDR & practical challenges
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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<b>EUDAME</b> (04/23) (01/24) (02/24)	) (0324) (04/24) (01/25) (03/26) (	Blue colour represents development Q4'26 Q1'27 Q2'27 Q3'27 Q4'27 Q2'29
Actor		
Devices		
Certificates		
MSU		
Vigilance		The CI/PS audit will also include a dobal audit of
CI/PS	CI/PS	the 6 modules together
Audit	First 5 Modules	
Transitional Period		6 months 18 months
Stabilisation of the system for the audit Publication of the notice of EUDAMED fu Mandatory use of the module as per Article Use of EUDAMED for Devices and Certifica	·	23 (3) (e) MDR/113 (3) (a) IVDR

National implementations

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