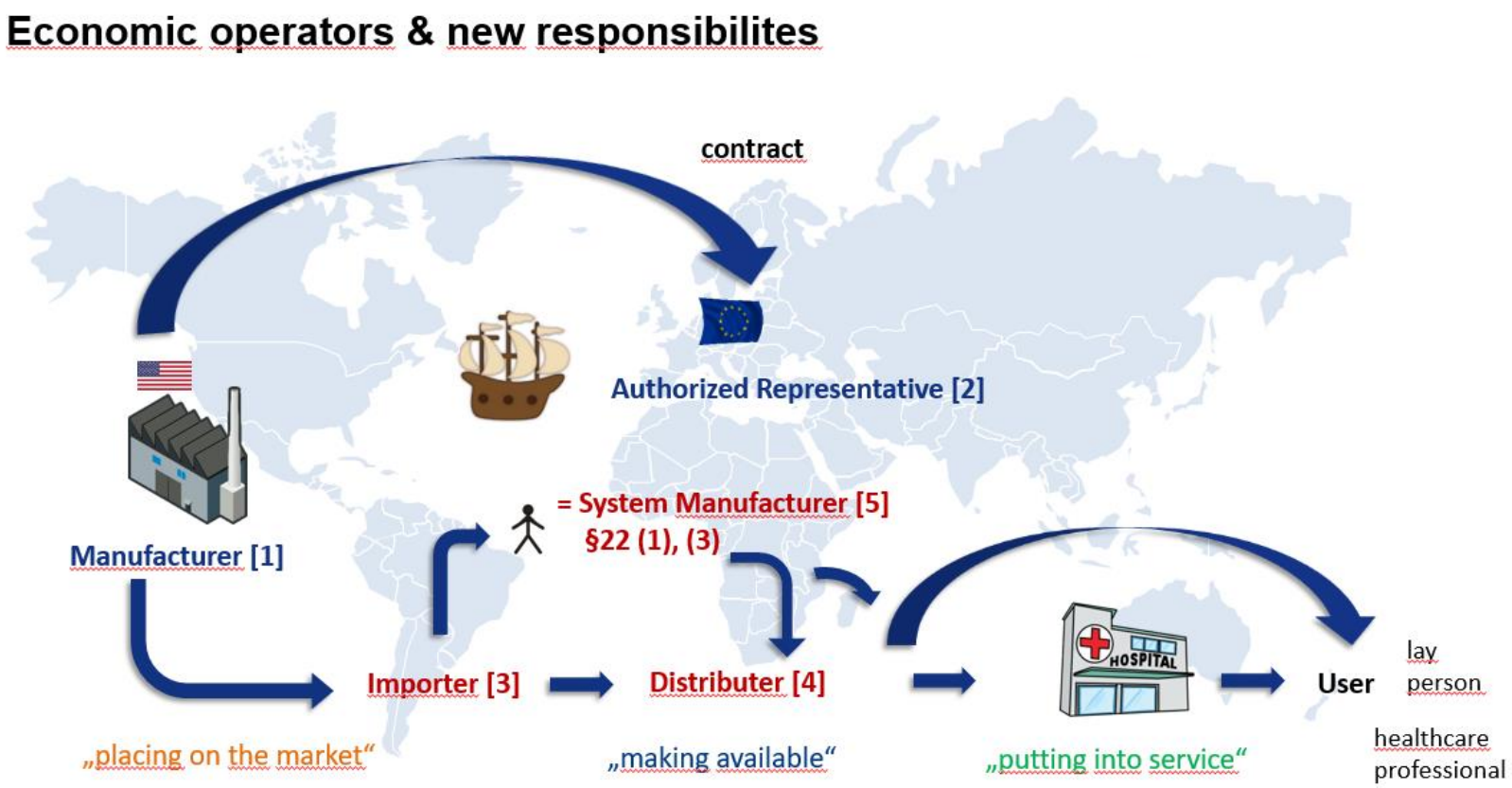
Planning for MDR Implementation Budget



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Costs related to MDR Implementation

1. Impact on **Quality Management System**(s)
   ► effort to establish (or up-date) SOP(s), proper implementation, training

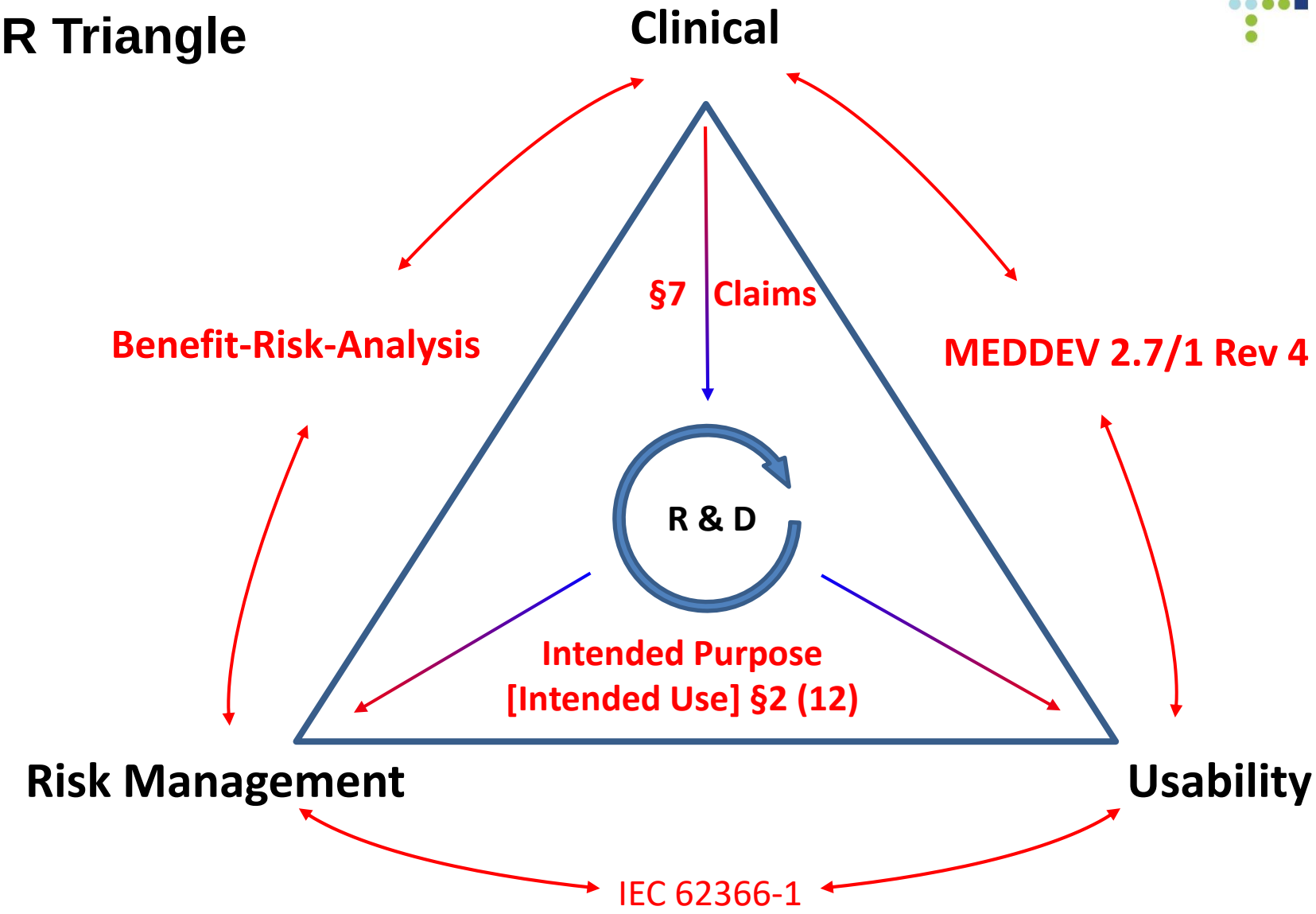
2. **Documentation efforts**
   ► review and up-date / split-up of Technical Files (remediation)

3. **Structural change** within
   ► one-time effort
   ► continuous additional effort

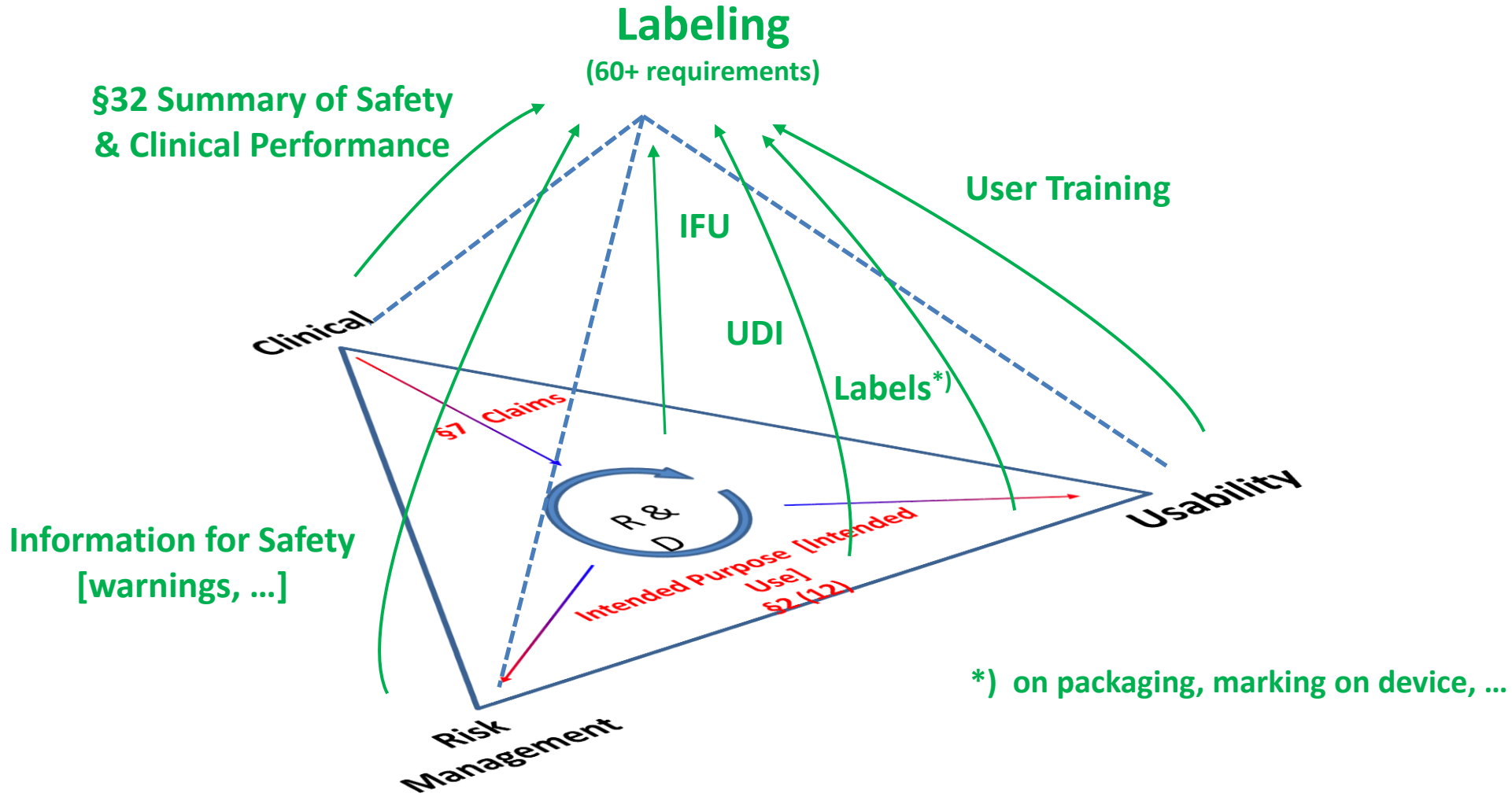
4. **Uncertainty** caused by Delegated & Implementing Acts

5. **Communication** efforts based on the number of stakeholders per topic

The MDR Triangle

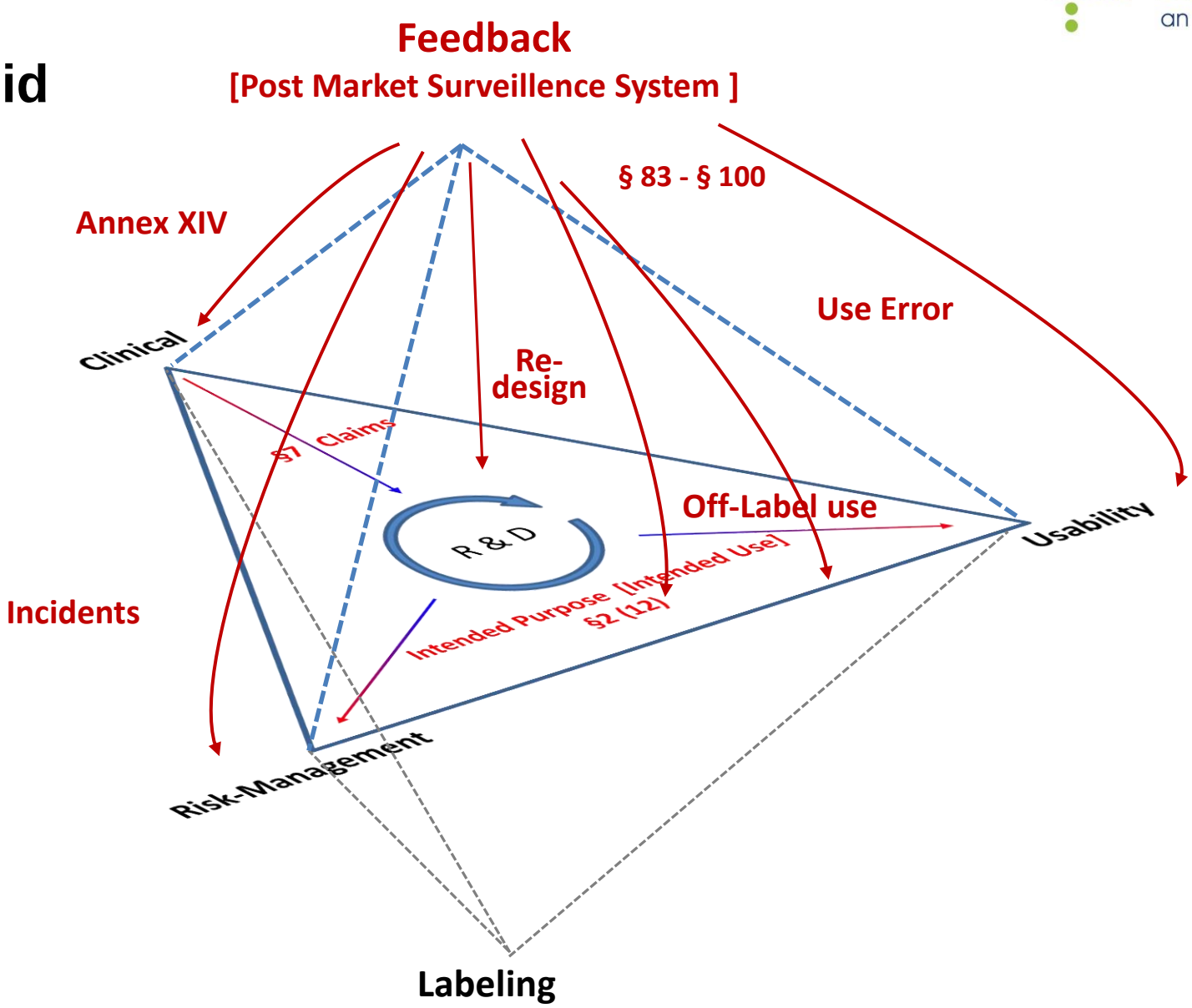


The „Triangular Pyramid“



*) on packaging, marking on device, …

The „double“ Triangular Pyramid



Formula to budget cost for MDR implementation

30 Δ x factor + # TechFiles x 2,5 Δ = cost

factor = add 0,25 per additionaal Business Unit QMS

Example: „1 Corporate + 2 BU“ QMS **50 TechFiles**

30 Δ x 1,5 + 50 x 2,5 Δ = 170 Δ

Δ = 20 days of work ~ 14 Man-Year

QM related efforts to comply with Medical Device Regulation (MDR)

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Chapter I	**(0,5 Δ)**	Scope & Definitions
Chapter II	**6,5*Δ**	Making available and putting into service of devices, obligations of economic operators, reprocessing, CE-marking, free movement [* includes processes for RM+UE]
Chapter III	**8,0 Δ (incl. Labeling, UDI)**	Identification and traceability of devices, registration of devices and of economic operators, summary of safety and clinical performance, EU databank on medical devices
Chapter IV	**2,0 Δ**	Notified Bodies [= Strategy how to select & work with NB(s)]
Chapter V	**1,5 Δ**	Classification and Conformity Assessment
Chapter VI	**4,5 Δ**	Clinical evaluation and clinical investigation
Chapter VII	**7,5 Δ**	Post-Market surveillance, vigilance and market surveillance
Chapter VIII	**(0,0 Δ)**	Coordination Group (MDCG), Expert laboratories, Expert panels and device registers
Chapter IX	**(0,5 Δ)**	Confidentiality, data protection, funding, penalties
Chapter X	**(0,5 Δ)**	Final provisions
Total	**~ 30 Δ**	for new or up-dated process descriptions (SOPs, Policies, etc.)

More efforts related to TechFiles & Annexes of the new MDR

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I	2,0 Δ	General Safety and Performance Requirements
II	0,2 Δ	Technical Documentation
III	??? Δ	**Technical Documentation on Post-Market Surveillance**
IV		EU Declaration of Conformity
V		CE Marking of Conformity
VI	0,2 Δ	Registration of Devices and Economic Operators / UDI
VII		Requirements to be met by Notified Bodies
VIII	0,1 Δ	Classification Rules
IX		Conformity Assessment based on a Quality Management System and on Assessment of the Technical Documentation
X		Conformity Assessment based on Type Examination
XI		Conformity Assessment based on Product Conformity Verification
XII		Certificates Issued by a Notified Body
XIII		Procedures for Custom-Made Devices
XIV	??? Δ	Clinical Evaluation and **Post-Market Clinical Follow-up**
XV	??? Δ	**Clinical Investigation**
XVI		List of Groups of Products without an Intended Medical Purpose
XVII		Correlation Table

2,5 Δ per TechFile as average (without Post-Market follow-ups)

The “cost driver” for MDR compliant TechFiles:

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	Cost driver *related to new requirements on*	Effect on	# of MDR Articles *due to new requirements*	Estimated # *days of work*
1	Clinical	CER Update [~MedDev 2.7.1 Rev 4]	Evaluation § 61 Investigation §62-82	**15 .. 20 days**
2	Risk Management	FMEA → Hazard/Risk based [Probability of Occurrence of Harm]	Annex I GSPR 1-9	**5 .. 10 days**
3	Usability	no USE ERROR true commitment! [~ IEC 62366-1 + FDA Guidance]	Annex I GSPR 5	**5 .. 10 days**
4	Labeling	Consistency & Validity of all labeling information (+ UDI)	Annex I GSPR 23	**10 .. 25 days**
5	PMS	Living all Feedback Loops [Annual PMS and Clinical Follow-ups]	PMS, … §83 - 100	**5^{+}..15^{+} days**
6	Editorial Updates	Review of Intended Purpose Rewrite TechFile contents	Annexes II + III	**4 .. 8^{+} days**

2,5 Δ = ~ 2,5 month = ~ 50 days

Pre-Markt: **39 .. 73^{+} days**

Post-Markt: **5^{+}.. 15^{+} days**

Budget estimates for MDR transition for BU