ISO 20916 IVD - Clinical performance studies

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Dr Marco Rost - Training Lead Regulatory Service (IVD)

Disclaimer

- Information presented within this webinar is based on our current understanding of the IVDR and the standards
- Subject to change

Why a webinar on a standard…

…in a series on IVDR?

- IVDR has expanded stipulations for clinical performance studies
- e.g. in Article 57 to 77 and in Annex XIII, section 2
- BS ISO 20916:2019 can assist in meeting those by Good Study Practice

Which of the following standards do you already know?

a) EN 13612

b) ISO 14155

c) ISO 20916

d) All of the above

e) None of the above

Context of standards

EN 13612

- IVD-specific
- 7 clauses

ISO 20916

- IVD-specific
- 9 clauses

(common structure)

ISO 14155

- Medical Devices (excludes IVD)
- 9 clauses

(common structure)

Specimens

Specimen

Discrete portion taken from the body

Archived

from repositories
e.g. tissue banks

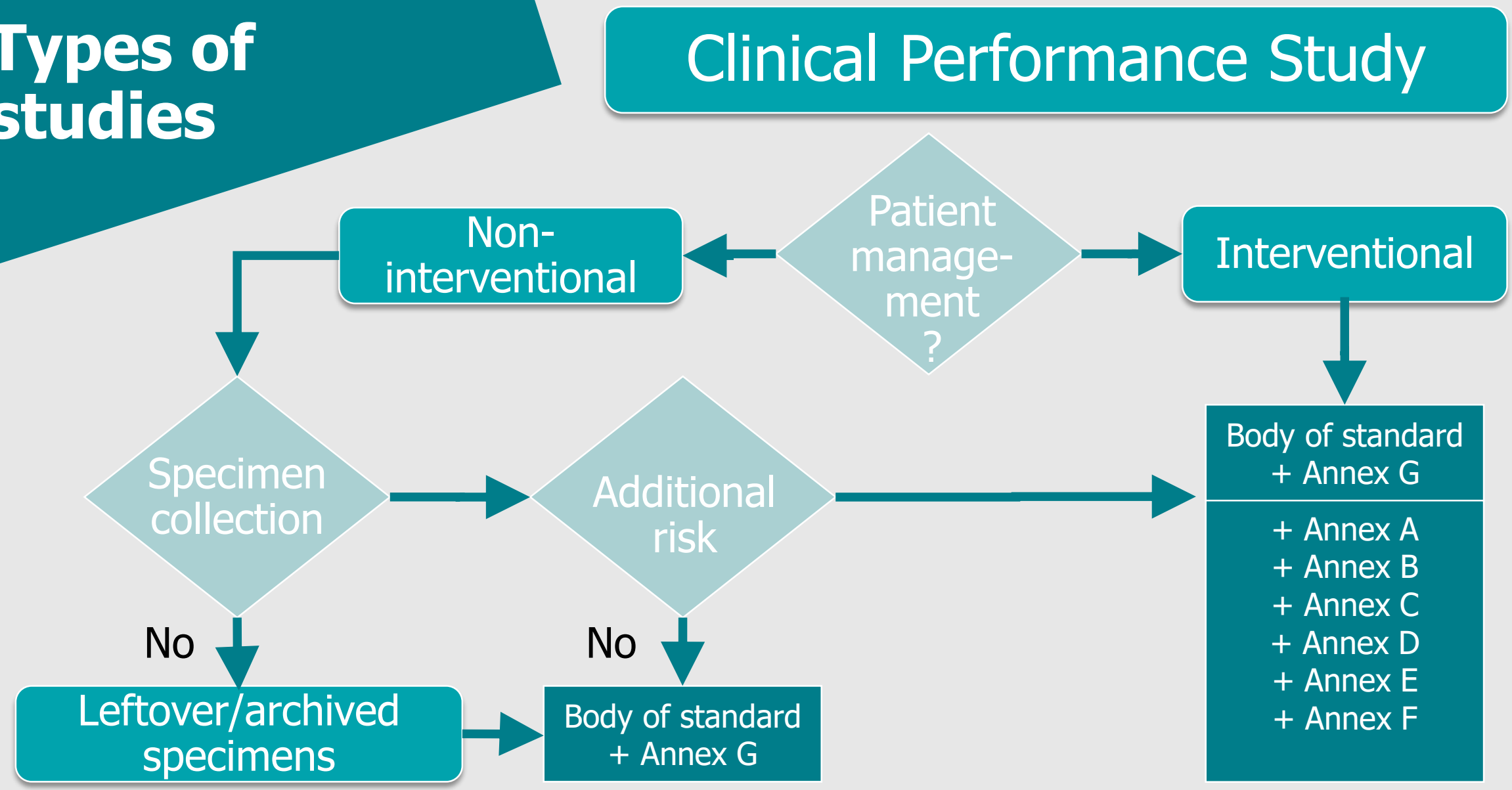
Leftover

unadulterated remnants after all standard analysis has been performed

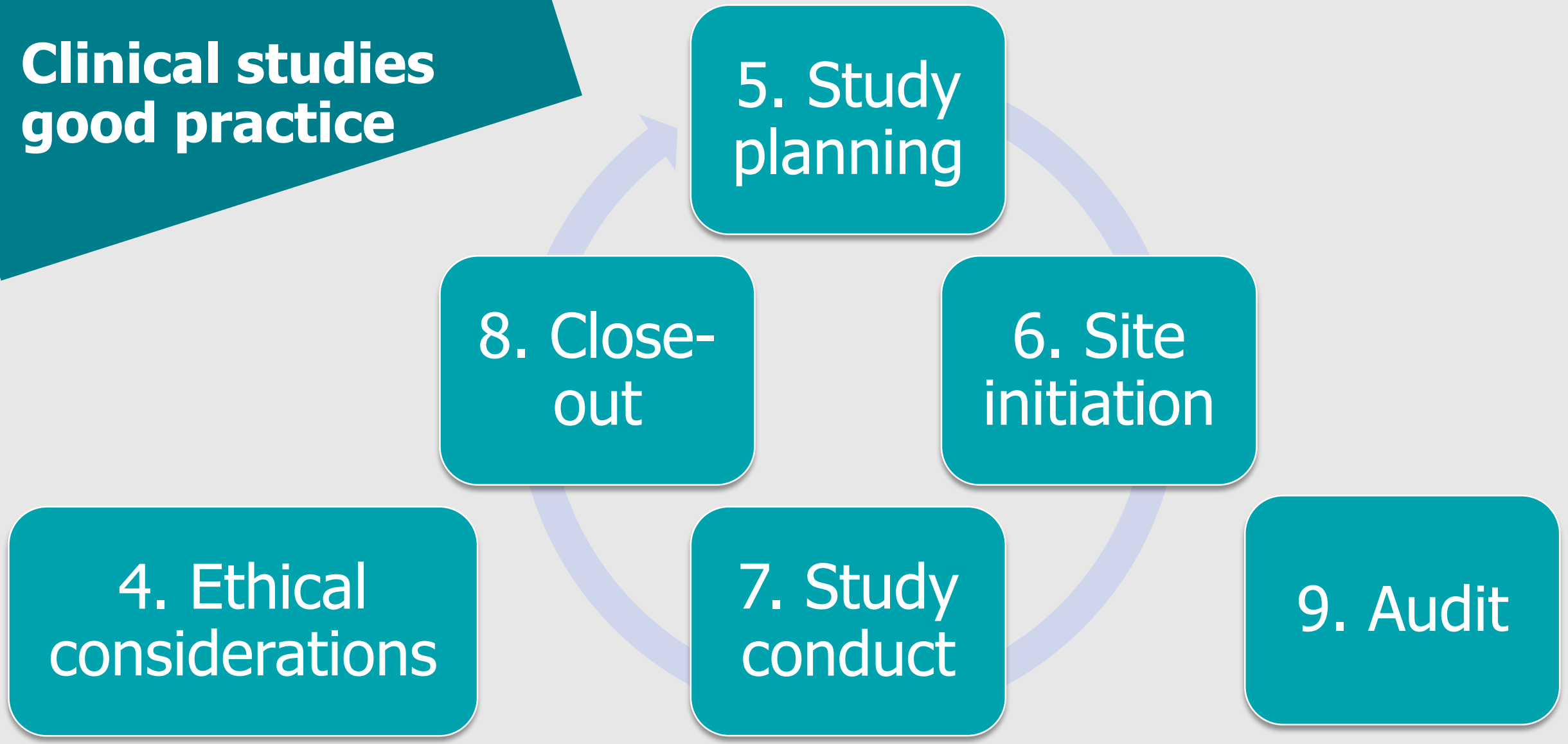
Sample

representative parts taken from a specimen

Types of studies



Clinical studies good practice



Ethical Consideration

4.1 General	• Protect rights, safety, dignity and well-being of the subjects
4.2 Improper influence or inducement	
4.3 Responsibilities	• all parties involved
4.4 Ethics committee involvement	• Caveat: Local law, e.g. for medical practititioner
4.5 Informed consent	• For leftover/archived specimens consent might be in general form

Are you planning to conduct a Clinical Performance Study under the IVDR this year or next year?

a) Yes

b) No

c) Evaluating at the moment

d) Not sure

5 Study planning

Need for QMS

Clinical Performance Studies shall

5.1	5.3	5.1
Be undertaken under an effective quality management system	Use product representative of the final IVD	Have agreements with externals - written and assumed
e.g. ➢ ISO 13485	e.g. ➢ Process control	5.11 e.g. ➢ Investigators ➢ CRO, labs

Some planning documents

compare IVDR Annex XIII.2.3.2 Clinical Performance Study Plan

5.4 Investigators Brochure	• Non-annex-A studies: Instruction for Use might be okay
5.5 Clinical Performance Study Protocol (CPSP)	• high quality, accurate and reliable data • For annex-A-studies: plus Annex B
5.10 Monitoring plan	• Extent based on risk • Rationale for remote monitoring

Annex H

Good clinical performance study documentation

- Informative
- Sets of documentation

Left-over/ Archived specimen

Interventional or addtitional risk

No.	Documentation	Purpose or comment	Relevant clause (set A)	Reference clause (set B)
H.1	Ethics committee notification, correspondence and opinion/approval	Gives evidence that a qualified, independent ethics committee has reviewed the clinical performance study and is maintaining oversight	4.4 4.5 5.5.3.18 b)	4.4 4.5 5.5.3.18 b)

Accountability

Of IVD devices

5.5.3.16

- Records about physical location of all IVD

Of specimens

5.7 & 5.8

- e.g. study sample log
- Ensure access to data
- E.g. for monitoring, audits, inspections

Study site initiation

6.1 General	• Initiation visit
6.2 Prerequisites	• Are determined
6.3 Training	• Includes updates/changes • Ensure documentation
6.4 Initiation of the study site	• Conducting staff ready • Pre-study documentation complete

Study conduct

7.1 General	• Start only after EC's or authorities' endorsement, if needed
7.2 Responsibilities of sponsor	• Compare Principal investigator responsibilities in 5.5.2 (CPSP)
7.3 Study site monitoring	• Focus of next slide
7.4 Data security & confidentiality	• Keep privacy and confidentiality • See 4.5: de-identify specimens

Monitoring

Verifies conduct conforms to

- CPSP
- ISO 20916
- Ethical &
- Regulatory requirements

Auditing – annex I

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- Separate from monitoring
- If deficiencies, re-audit

Auditors

- Qualified
- No direct responsibility for site or study

Audit

- Written procedures
- Specific plans

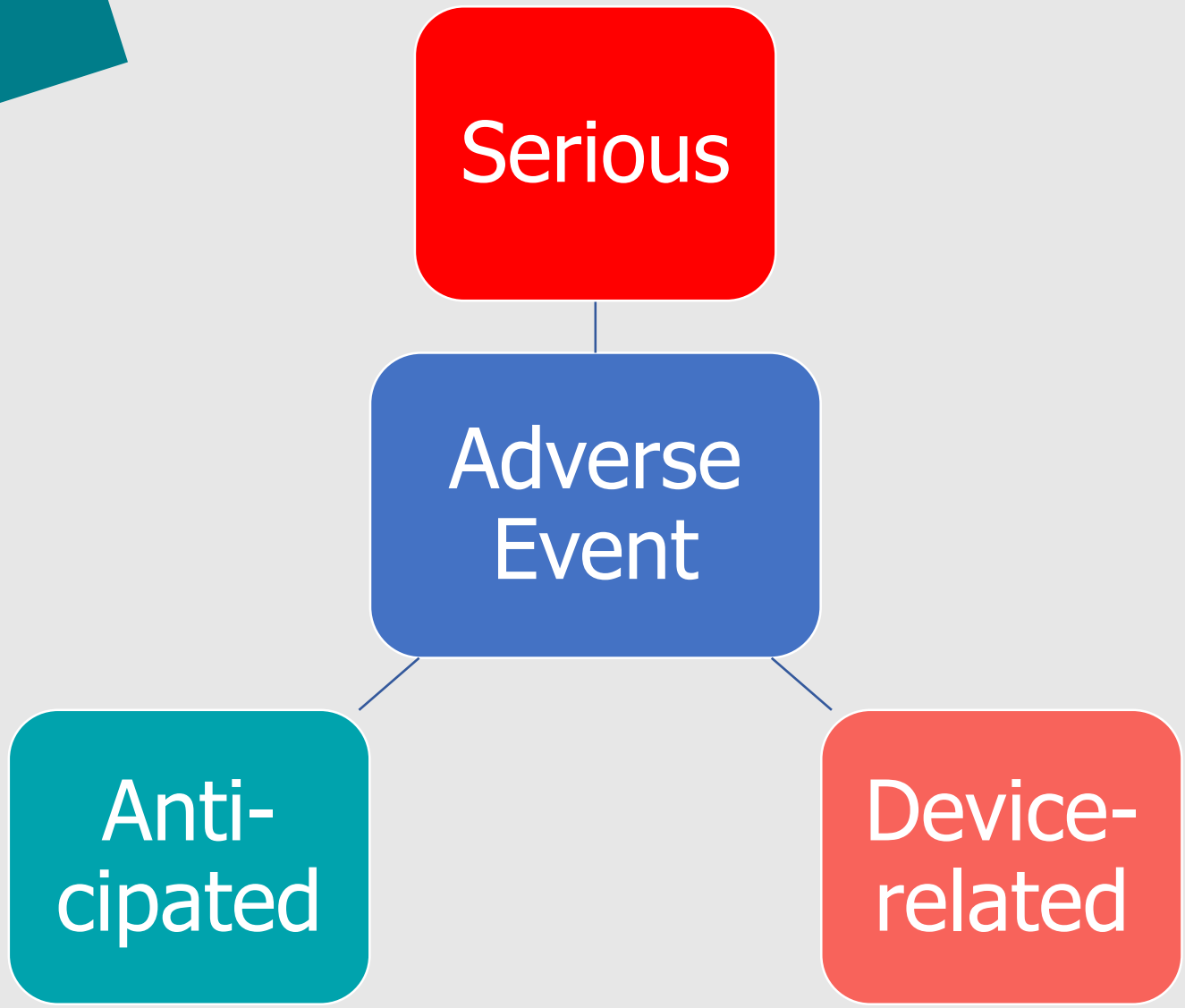
Adverse Event or device effect

Adverse Event	Adverse Device Effect	**Incident**
• In context of the study	+ Related to use of IVD	• Differently defined in IVDR

IVDR mentions abnormal laboratory finding

IVD must be made available

AE categorization Annex G



Study close-out

8.1 Close-out activities	• Complete records • notify relevant parties
8.2 Clinical performance study report	• IVDR within 1 year and • Publically available in EUDAMED
8.3 Document retention	• According to regulatory and QMS requirements
8.4 Suspension or premature termination	• Inform relevant parties • IVDR: Study report within 3 months

Summary

ISO 20916

- Details Good Study Practice
- Takes into account the specifics of IVD
- Has a modular structure
- Helps in addressing requirements of IVDR

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