



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Anonymisation Report Template

Structured fields format

Clinical Data Publication (Policy 0070) relaunch - EMA webinar

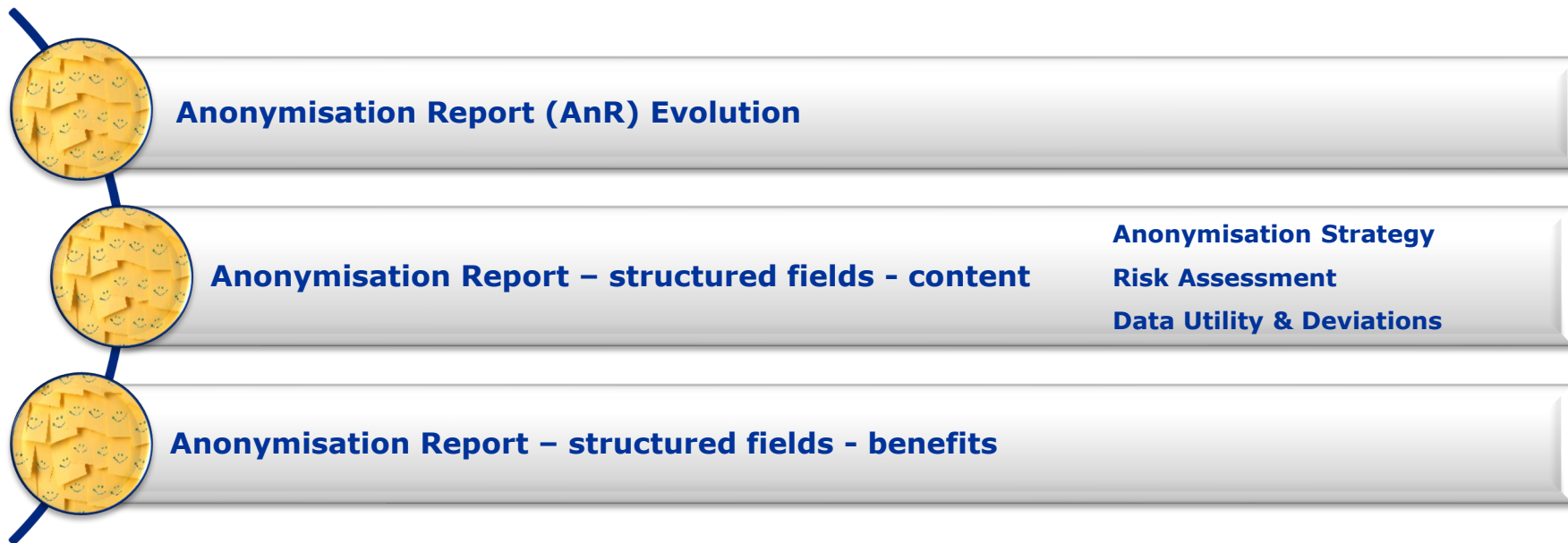
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An agency of the European Union



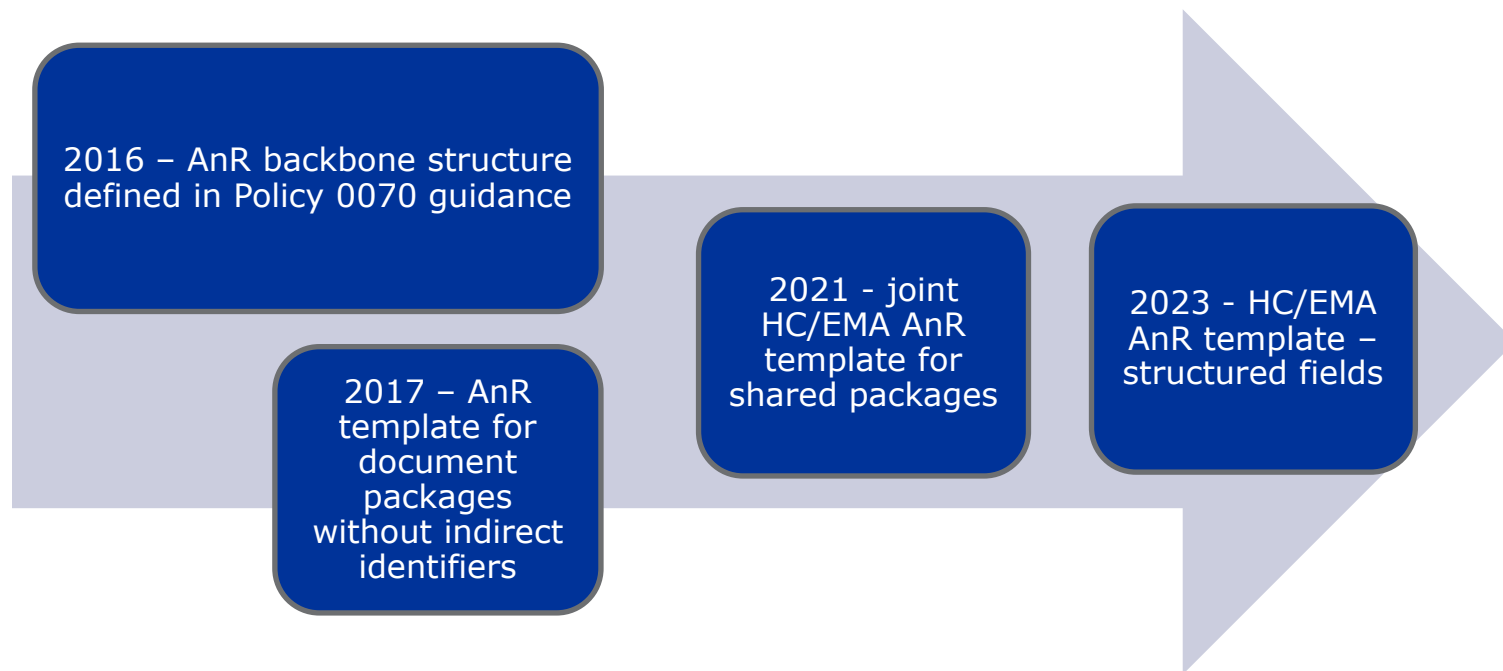


Contents





Policy 0070 - Anonymisation Report (AnR) Evolution





AnR Template Content (1/3) – Anonymisation Strategy

Anonymisation approach

- Tick boxes (quantitative / qualitative)

Personal data variables – presented in a tabulated manner

- Columns for category of data subject & anonymisation technique
- Fields will contain predefined values (drop-down lists)

No free text box



AnR Template Content (2/3) – Risk Assessment

Description of reference population

- Targeted questions on size and definition of the reference population
- Targeted questions on rare disease and special population categories

Risk assessment

- Initial risk of reidentification, selected risk threshold and residual risk

Free text box

- Explain the anonymisation strategy



AnR Template Content (3/3) – Data Utility & Deviations

Data variables bearing the highest data utility

- 5 most important personal data variables
- Extent of the data utility preservation

Aggregated data

- Expected to be disclosed in full
- Blinding redactions to be documented in the deviation section

Narratives

- Expected to be anonymised
- Redaction in full considered a deviation



Anonymisation Report Template – structured fields - benefits

	Applicants	✓ Content predictability ✓ Writing efficiency ✓ Consistency ✓ Content quality ensured ✓ One report for joint EMA/HC packages
	Regulators	✓ Review efficiency ✓ EMA/HC workshare
	Portal Users	✓ Concise ✓ Easier to understand ✓ Facilitates the identification of key information - Data utility considerations - Data transformations



Any questions?

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