Good AI Practice – When Ethical Literacy Becomes Part of the Job

DR KAMILA DUNIEC

PHUSE SDE UTRECHT 2026

Statistical Programming

- easy money?

- What are we paid for?

What is Compliance for us?

- Following the SOPs and guidelines
- ICH GCP
- Technical conformance guides
- CDISC standards
- Ensuring there is evidence and traceability
- Being audit-ready

Compliance in Practice (so far)

A mix of business (manual) process and system rules

DATA FLOW	DEVELOPMENT CYCLE	GENERAL
• Data privacy • Data security • Record integrity • Reproducibility • Traceability	• QC process • Double programming • Oversight • Vendor selection	• Transparency • Documentation • Responsibility matrix • Adequate training • Validated tools and systems

AI – a compliance disruptor?

DATA FLOW

- Is data for algorithm training used according to IC?
- How is record integrity demonstrated without reproducibility and traceability?

DEVELOPMENT CYCLE

- Shadow use
- Double programming – how long?
- Human oversight in practice?
- Are AI-based tools validated?

GENERAL

- Transparency
- How do we document the algorithm?
- Who is responsible?
- Does everyone have adequate training in AI algorithms?

Frameworks and Regulations (selection)

- 2018 The Montréal Declaration for a Responsible Development of Artificial Intelligence
- 2019 IEEE: Standards Association: Ethically Aligned Design
- 2019 European Commission: Ethics guidelines for trustworthy AI
- 2021: WHO: Ethics and Governance of AI for Health
- 2021 UNESCO Recommendation on the Ethics of AI
- 2021 FDA/Health Canada/MHRA: Good Machine Learning Practice for Medical Device Development: Guiding Principles
- 2023 MHRA: Guidance on AI as a Medical Device
- 2024 EMA: Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle
- 2024 EU AI Act
- 2025 FDA: Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products (The 7-Step Framework)
- 2026 EMA&FDA: Guiding principles of good AI practice in drug development
- 2026 Korea AI Basic Act: „protecting the Rights and Interests of the People and their dignity, contributing to improving the quality of life of the people”

Frameworks and Regulations (selection)

- 2018 The Montréal Declaration for a **Responsible** Development of Artificial Intelligence
- 2019 IEEE: Standards Association: **Ethically** Aligned Design
- 2019 European Commission: **Ethics** guidelines for trustworthy AI
- 2021: WHO: **Ethics** and Governance of AI for Health
- 2021 UNESCO Recommendation on the **Ethics** of AI
- 2021 FDA/Health Canada/MHRA: Good Machine Learning Practice for Medical Device Development: Guiding Principles
- 2023 MHRA: Guidance on AI as a Medical Device
- 2024 EMA: Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle
- 2024 EU AI Act: "human-centric and **trustworthy** artificial intelligence (AI), (…) protection of health, safety, fundamental rights (…) including democracy, the rule of law and environmental protection, against the harmful effects of AI systems"
- 2025 FDA: Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products (The 7-Step Framework)
- 2026 EMA&FDA: Guiding principles of **good AI practice** in drug development
- 2026 Korea AI Basic Act: „protecting the Rights and Interests of the People and their **dignity**, contributing to improving the quality of life of the people"

Compilation

Old

- Risk-based approach
- Adherence to standards
- Clear context of use
- Data governance and documentation

New

- Ethical foundations, social responsibility, and human accountability
- Model development, validation, and periodic re-evaluation
- Data input - confidentiality, representativeness
- Transparency & explainability

Is it REALLY relevant?

No

- Applications are limited
  - Knowledge base chatbot
  - Code generation (1st line only)
  - Code comparison (plagiarism)
  - Code migration (SAS to R)
- Human control is maintained
- All computerized systems and tools are validated
- Analyses are pre-defined
- Standards and quality checks

Yes

- FDA
  - Single trial submissions
  - *In silico* clinical trials
  - Digital clones
  - Assess occurence of clinical events from social media during a clinical trial
- EU AI Act (Aug 2026)
  - AI literacy of all personnel (Art.4)
- Compliance gap

Ethical literacy is a technical skill

What

- what makes a bad model
  - representativeness of data
- bias detection
- model drift
- ethical reasoning
- social impact assessment

How

- Self-assessment tool
  The assessment list for trustworthy artificial intelligence (European Commission, ALTAI)
- Worst case scenario
  - Train the brain to look for "what could go wrong"
  - Scenario: "Assume this AI model caused a major regulatory rejection or a patient safety issue two years from now. What went wrong?".

    Look for "blind spots" in the data and logic

Image source: Flaticon.com

What are we paid for?

Combination of:

technical expertise, compliance, and ethical judgement

Image source: Flaticon.com

Thank you