# AI-Assisted Root Cause Analysis: Can Artificial Intelligence Improve Pharmaceutical Investigations?

*A practical GMP article for deviation investigations, CAPA, and quality system improvement*

Root cause analysis is one of the most important skills in pharmaceutical Quality Assurance. A deviation may be documented correctly, reviewed on time, and closed with a CAPA - but if the root cause is wrong, the same problem can return again under a different deviation number.

That is why AI-assisted root cause analysis is such a strong topic for pharmaceutical QA. Artificial intelligence could help investigators retrieve similar historical events, identify recurring patterns, compare investigation language, detect weak CAPA themes, and reduce the tendency to treat every event as isolated. But AI should not become the investigator. In GMP, the responsibility for determining root cause, product impact, CAPA adequacy, and batch disposition must remain with qualified human personnel and the Quality Unit.

FDA requires unexplained discrepancies and batch failures to be thoroughly investigated, whether or not the batch has already been distributed. The investigation must extend to other batches of the same drug product and other drug products that may have been associated with the failure or discrepancy, and a written record must include conclusions and follow-up (FDA, 21 CFR 211.192).

AI can support this expectation by helping investigators ask better questions and find relevant evidence faster. It cannot replace the scientific and GMP judgment required to close the investigation.

## Why Root Cause Analysis Matters in Pharmaceutical Investigations

Root cause analysis is the process of identifying the underlying cause, or causes, of a deviation, discrepancy, complaint, failure, or quality event. In pharmaceutical manufacturing, RCA is not just a problem-solving tool. It directly affects:

| RCA Output | GMP Consequence |
|---|---|
| Root cause conclusion | Determines whether the investigation is scientifically credible |
| Product impact assessment | Supports batch disposition and patient risk evaluation |
| CAPA plan | Determines whether recurrence is likely to be prevented |
| Similar-event review | Determines whether other batches, products, or systems are affected |
| Quality system trend | Supports APR/PQR, management review, and inspection readiness |
| Regulatory defensibility | Demonstrates whether the company understands its |

| | |
|---|---|
| | process and failures |

FDA's quality systems guidance describes CAPA as a CGMP concept focused on investigating, understanding, and correcting discrepancies while attempting to prevent recurrence. The guidance specifically includes root cause analysis with corrective action as a way to understand the cause of a deviation and potentially prevent recurrence of similar problems (FDA, Quality Systems Approach to Pharmaceutical CGMP Regulations).

ICH Q10 also expects a structured investigation approach with the objective of determining root cause, with the level of effort, formality, and documentation commensurate with the level of risk (ICH Q10).

The key idea is simple: a weak RCA creates weak CAPA. Weak CAPA creates repeat deviations.

## Traditional RCA Methods in Pharmaceutical QA

Pharmaceutical investigations commonly use several traditional RCA tools. These tools are still valuable and should not be replaced by AI.

| RCA Tool | How It Helps | Common Weakness |
|---|---|---|
| 5 Whys | Pushes the investigator beyond the obvious symptom | Can become shallow if the questions are not evidence-based |
| Fishbone / Ishikawa diagram | Organizes possible causes by category | Can become a checklist exercise without proof |
| Fault tree analysis | Builds logical pathways to failure | Requires strong technical understanding |
| Event timeline | Clarifies sequence of events | Often incomplete when records are fragmented |
| Is/Is Not analysis | Defines boundaries of the problem | Requires accurate comparative data |
| FMEA | Evaluates failure modes, severity, occurrence, detection | Can become subjective if scoring is weak |
| Pareto analysis | Identifies high-frequency categories | May miss low-frequency high-risk events |
| Similar-event review | Identifies recurrence and systemic issues | Often limited by poor searchability |

AI can enhance these methods, but it should not bypass them. A good AI tool should help the investigator populate the fishbone with evidence, retrieve similar historical deviations, challenge a weak 5 Why chain, and identify missing data. It should not simply generate a confident root cause conclusion.

## The Problem With Traditional Investigations

Many pharmaceutical investigations struggle for predictable reasons.

| Investigation Weakness | Practical GMP Risk |
|---|---|
| “Human error” used as root cause | CAPA becomes retraining instead of system correction |
| Similar events missed | Repeat deviations appear unrelated |

| | |
|---|---|
| Poor event timeline | Sequence of failure is unclear |
| Narrow investigation scope | Other batches, equipment, products, or shifts are not assessed |
| Confirmation bias | Investigator favors the first plausible explanation |
| Weak evidence linkage | Conclusion is not supported by records |
| CAPA not linked to root cause | Action does not prevent recurrence |
| Effectiveness check too weak | CAPA is closed without proving improvement |
| Trend review delayed | Systemic issue is identified months later |
| Copy-paste investigation language | Investigations become repetitive and superficial |

FDA's quality systems guidance emphasizes that discrepancies should be documented and handled appropriately, and that a discrepancy investigation process is critical when a discrepancy affecting product quality is found. It also states that investigation, conclusion, and follow-up must be documented under 21 CFR 211.192.

This is exactly where AI can help: not by deciding the answer, but by improving the completeness, consistency, and evidence base of the investigation.

## Investigation Bias: Why Human Judgment Needs Support

Investigators are human. That means they can be affected by bias, time pressure, workload, and organizational habits.

| **Bias** | **Example in a GMP Investigation** |
|---|---|
| Confirmation bias | Investigator focuses only on evidence supporting the first suspected cause |
| Recency bias | Recent similar deviation is assumed to be the cause |
| Availability bias | The most familiar cause is selected because it is easy to recall |
| Department bias | Root cause is assigned to another department without full evidence |
| Outcome bias | Investigation is judged by whether batch was rejected or released, not by investigation quality |
| Normalization of deviance | Recurring small failures are accepted as "normal" |
| Training bias | Every operator error becomes a training CAPA |

ICH Q9(R1) explicitly recognizes subjectivity as a risk to quality risk management decisions and states that subjectivity should be managed and minimized (ICH Q9(R1)).

AI can help reduce some forms of bias by forcing broader evidence retrieval. For example, it can retrieve similar events across departments, shifts, products, and years, even when the investigator does not remember them. But AI can introduce its own bias if trained on weak historical investigations. If the historical database is full of "human error" conclusions, AI may learn to suggest the same weak pattern.

## How AI Could Support Root Cause Analysis

AI-assisted RCA is best understood as investigation support, not investigation automation.

| AI Capability | Investigation Use |
|---|---|
| Similar-event retrieval | Finds prior deviations, complaints, OOS, CAPAs, and investigations with similar patterns |
| Natural language processing | Searches narrative text even when wording differs |
| Pattern recognition | Detects recurring causes across equipment, shifts, products, rooms, or suppliers |
| Timeline building | Pulls related timestamps from batch records, alarms, EM, LIMS, MES, and QMS |
| Fishbone support | Suggests possible cause categories based on event type |
| 5 Why challenge | Identifies unsupported leaps in logic |
| CAPA comparison | Checks whether proposed CAPA matches the stated root cause |
| Effectiveness review | Compares recurrence before and after CAPA |
| Trend analysis | Detects repeated investigation themes |
| Product impact support | Identifies potentially affected batches, materials, equipment, or systems |

The best AI output is not “the root cause is X.” A safer and more useful output is: “Here are five similar historical events, three possible recurring patterns, two missing data points, and four impact areas that require human review.”

That kind of output strengthens the investigator instead of replacing the investigator.

## AI-Assisted Similar-Event Retrieval

Similar-event review is one of the most valuable and realistic AI use cases.

Traditional QMS searches often depend on exact keywords or deviation categories. But deviations are written by different people using inconsistent language. One investigator may write “operator intervention,” another may write “manual adjustment,” another may write “line stoppage,” and another may write “operator corrected jam.”

AI can use semantic search to find related events even when the wording is different.

| Current Deviation | AI-Detected Similar Events |
|---|---|
| Filling needle drip observed during batch setup | Prior deviations involving fill-volume variation, dripping needle, pump pulsation, stopper wetness, rejected vials |
| Balance failed daily verification | Prior calibration failures, vibration complaints, relocation change control, analyst comments |
| HEPA pressure alarm during cleaning | Prior HVAC alarms, maintenance work orders, pressure recovery deviations, EM excursions |
| OOS assay result | Prior method issues, reference standard changes, analyst training, sample preparation deviations |

This is especially useful because 21 CFR 211.192 requires investigations to extend to other batches of the same drug product and other drug products that may have been associated with the failure or discrepancy. AI can help identify those potentially associated records faster.

## AI Pattern Recognition Across Investigations

AI can detect patterns across large investigation datasets that humans may not easily see.

| Pattern Detected | Possible Meaning |
|---|---|
| Same equipment repeatedly linked to deviations | Maintenance, setup, qualification, or design issue |
| Same shift has more line clearance errors | Training, staffing, supervision, or workload issue |
| Same supplier linked to material complaints | Supplier process variation or specification weakness |
| Same SOP cited in multiple deviations | Procedure clarity or training issue |
| Same CAPA type repeatedly used | Weak corrective action culture |
| Same product shows recurring yield loss | Process robustness issue |
| Same root cause category appears after retraining | Training did not address true cause |

ICH Q10 expects pharmaceutical companies to use process performance and product quality monitoring systems that include internal and external feedback such as complaints, product rejections, non-conformances, recalls, deviations, audits, and regulatory findings. AI can help connect these sources rather than treating each quality event as separate.

## AI and 5 Why Analysis

The 5 Why method is simple, but it is often misused.

A weak 5 Why may look like this:

| Question | Weak Answer |
|---|---|
| Why did the operator use the wrong form? | Because the operator made a mistake |
| Why did the operator make a mistake? | Because they were not paying attention |
| Why were they not paying attention? | Because they need retraining |
| Root cause | Human error |
| CAPA | Retrain operator |

An AI-assisted 5 Why review could challenge this logic:

| AI Prompt | Investigation Value |
|---|---|
| Was the correct form available at point of use? | Checks document control/access issue |
| Were obsolete forms removed? | Checks version control issue |
| Did other operators make same error? | Checks systemic issue |
| Was the form number similar to another form? | Checks design/human factors issue |
| Was the task performed under time pressure? | Checks workload/environment issue |
| Was training completed before task assignment? | Checks LMS/training effectiveness |
| Did procedure clearly identify the form? | Checks SOP clarity |

A good AI tool should make weak investigation logic harder to ignore.

## AI and Fishbone Diagrams

Fishbone diagrams can be useful, but they often become generic. AI can help make them evidence-based.

For a sterile manufacturing deviation, AI may suggest categories such as:

| Fishbone Category | AI-Supported Evidence Search |
|---|---|
| People | Training records, prior operator deviations, qualification status |
| Method | SOP clarity, batch record instructions, recent revisions |
| Machine | Equipment alarms, maintenance history, calibration status |
| Material | Supplier lot, COA, incoming inspection, material deviation history |
| Measurement | Test method, analyst, instrument, standard, LIMS calculation |
| Environment | EM results, pressure alarms, temperature/humidity, cleaning records |
| Management/System | Staffing, schedule pressure, change controls, CAPA recurrence |

The investigator still determines what is relevant. AI helps ensure the investigation considers the right evidence.

## CAPA Effectiveness Evaluation

A CAPA is only useful if it reduces or eliminates recurrence. AI can support CAPA effectiveness review by comparing pre-CAPA and post-CAPA event patterns.

| CAPA | AI Effectiveness Check |
|---|---|
| Retrained operators on line clearance | Did line clearance deviations decrease after training? |
| Revised cleaning SOP | Did cleaning deviations or residue findings decrease? |
| Replaced equipment part | Did related alarms, rejects, or deviations decrease? |
| Added second-person verification | Did documentation errors decrease, or did errors shift elsewhere? |
| Updated supplier specification | Did incoming material deviations decrease? |

ICH Q10 states that CAPA should result in product and process improvements and enhanced product and process understanding, and that CAPA effectiveness should be evaluated. AI can help evaluate effectiveness more objectively by scanning recurrence patterns across the QMS.

## Practical Workflow: AI-Assisted Investigation

```
Deviation opened
        ↓
Initial event description entered
        ↓
AI retrieves similar events, CAPAs, complaints, OOS, equipment history
        ↓
Investigator reviews AI findings
        ↓
AI suggests missing data sources and possible impact areas
        ↓
SMEs perform evidence-based RCA using 5 Why, fishbone, timeline, etc.
        ↓
AI checks consistency between root cause, CAPA, and evidence
        ↓
QA reviews investigation and product impact assessment
        ↓
CAPA assigned and implemented
        ↓
AI supports CAPA effectiveness monitoring
        ↓
Investigation closed by authorized human reviewers
```

This model keeps the human investigator and QA in control.

## Investigation Case Studies

### Case Study 1: Repeated “Human Error” in Batch Record Entries

A manufacturing area has several deviations involving incorrect batch record entries. Each deviation is closed with “operator error” and retraining.

AI reviews historical deviations and detects that most errors occur in the same section of the batch record, during the same process step, and across multiple trained operators. It also identifies that the batch record instruction references an SOP section that was revised but not reflected in the batch record.

The investigation is expanded. The actual root cause is not lack of attention; it is a document design and cross-reference issue. CAPA includes batch record revision, SOP alignment, and targeted training.

Lesson: AI helps identify a systemic documentation problem hidden behind repeated “human error” conclusions.

### Case Study 2: OOS Investigation With Similar Historical Laboratory Events

A QC lab obtains an OOS assay result. The first hypothesis is sample preparation error.

AI retrieves similar OOS and invalid assay investigations from the prior two years. Several involved the same instrument, same method, and same reference standard handling step. It also finds a recent change control involving standard storage conditions.

The investigation expands beyond analyst technique. QC identifies a reference standard handling weakness and revises the procedure with additional controls.

Lesson: AI helps prevent premature closure based on the most convenient cause.

### Case Study 3: Environmental Monitoring Excursion in Sterile Manufacturing

A Grade B viable excursion occurs near an aseptic filling line. Initial review finds no obvious intervention failure.

AI retrieves prior EM excursions, HVAC alarms, maintenance work orders, cleaning records, and personnel monitoring events for the same room. It identifies a recurring pattern: excursions occur within 48 hours after a specific maintenance activity involving ceiling access.

The investigation includes engineering and microbiology. CAPA revises maintenance controls, post-maintenance cleaning, and EM monitoring after ceiling access.

Lesson: AI connects EM data with maintenance history that may not be obvious in a standard investigation.

### Case Study 4: CAPA Effectiveness Failure After SOP Retraining

A CAPA for repeated cleaning documentation errors required retraining. Three months later, AI detects the same error pattern in a different department using the same form.

QA reviews the CAPA and determines the original effectiveness check was too narrow. The issue was form design, not department-specific training.

Lesson: AI can detect recurrence across departments and challenge weak CAPA effectiveness conclusions.

## Risks of AI-Generated Root Cause Conclusions

AI can improve investigations, but it can also create new risks.

| AI Risk | GMP Impact | Control |
|---|---|---|
| AI suggests plausible but wrong root cause | Investigation closes incorrectly | Human evidence review required |
| AI overweights historical weak investigations | Repeats past poor RCA patterns | Curated training data and QA oversight |
| AI misses rare but critical cause | Product impact underestimated | Traditional SME review remains active |
| AI retrieves irrelevant similar events | Investigation becomes distracted | Investigator triage |
| AI creates false correlation | CAPA targets wrong system | Statistical and SME confirmation |
| AI-generated text is copied blindly | Weak or unsupported conclusions | Source-linked outputs and QA review |
| AI model changes over time | Investigation support becomes | Model version control and validation |

| | | |
|---|---|---|
| | inconsistent | |
| AI output not retained | Decision cannot be reconstructed | Audit trail and record retention |

The most dangerous AI error is not an obvious hallucination. It is a confident, well-written, but unsupported investigation conclusion.

## Validation and Part 11 Considerations

If AI is used inside a GMP QMS, deviation system, CAPA system, or investigation workflow, validation and data integrity controls may apply.

FDA Part 11 requires controls for closed systems that create, modify, maintain, or transmit electronic records, including validation for accuracy, reliability, consistent intended performance, and the ability to detect invalid or altered records. It also requires access limitation, audit trails, and controls over system documentation (FDA, 21 CFR Part 11).

For AI-assisted RCA, validation should address:

| Validation Area | Practical Question |
|---|---|
| Intended use | Is AI retrieving records, suggesting causes, drafting text, or ranking CAPA risk? |
| Source systems | Does AI search approved QMS records, LIMS, MES, CMMS, complaints, APR/PQR? |
| Data integrity | Are source records complete, accurate, and audit-trailed? |
| Output traceability | Can users see which records support the AI suggestion? |
| Model version | Is the AI model/configuration controlled? |
| Performance testing | Can AI retrieve known similar historical investigations? |
| False negatives | Does AI miss relevant similar events? |
| False positives | Does AI overwhelm users with irrelevant results? |
| Human override | Can investigators reject AI suggestions with rationale? |
| Audit trail | Are AI outputs, human decisions, and final conclusions retained? |
| Periodic review | Is AI performance reviewed over time? |

FDA Part 11 also requires secure, computer-generated, time-stamped audit trails that record operator actions creating, modifying, or deleting electronic records without obscuring previous information. If AI output influences a GMP investigation, the system should retain enough information to reconstruct the decision.

## Human Review Expectations

AI should not own root cause conclusions. A safe oversight model looks like this:

```
AI retrieves evidence
        ↓
Investigator evaluates evidence
        ↓
```

```
SMEs confirm technical plausibility
        ↓
QA challenges logic and product impact
        ↓
CAPA owner defines actions
        ↓
QA approves final investigation and CAPA
```

Human oversight is especially important when investigations involve:

- Batch rejection or release
- Sterility assurance
- OOS results
- Aseptic processing
- Cleaning validation
- Equipment failure
- Data integrity
- Repeated deviations
- Complaint trends
- Field alert or recall considerations
- Regulatory commitments

EMA's AI reflection paper states that AI risk depends not only on technology and data quality, but also on context of use and degree of influence. It also states that manufacturers are responsible for ensuring algorithms, models, datasets, and pipelines are fit for purpose and aligned with legal, ethical, technical, scientific, regulatory, and GxP standards (EMA, 2024).

That principle fits AI-assisted investigations perfectly: the more influence AI has on the RCA conclusion, the stronger the controls must be.

## Implementation Roadmap for AI-Assisted RCA

### Step 1: Start With Similar-Event Retrieval

The lowest-risk, highest-value starting point is using AI to find similar deviations, complaints, CAPAs, OOS events, equipment failures, and change controls.

### Step 2: Clean Historical Investigation Data

Standardize deviation categories, equipment IDs, product names, room numbers, root cause codes, CAPA types, and investigation metadata. AI cannot perform well on messy historical data.

### Step 3: Define Intended Use

Decide whether AI will retrieve similar events, suggest possible cause categories, draft investigation summaries, check RCA/CAPA alignment, monitor CAPA effectiveness, or rank recurrence risk. Each use has a different risk level.

### Step 4: Validate Based on Risk

Test the AI against historical investigations where related events are already known. Confirm that it retrieves relevant records without excessive irrelevant results.

### Step 5: Require Source-Linked Outputs

AI should always show the records, sections, timestamps, or data behind its suggestions. Unsupported conclusions should not be accepted.

### Step 6: Update Investigation SOPs

Procedures should define how AI may be used, how outputs are reviewed, and what must be documented.

### Step 7: Train Investigators

Investigators should understand both RCA methods and AI limitations. AI literacy should become part of investigation training.

### Step 8: Monitor Performance

Track relevant similar events found, missed related events, accepted versus rejected AI suggestions, repeat deviations, CAPA effectiveness, investigation cycle time, and QA comments related to weak RCA.

### Step 9: Scale Gradually

Start with advisory support. Do not allow AI to auto-select root cause, product impact, or CAPA approval.

## Comparison Table: Traditional RCA vs AI-Assisted RCA

| Area | Traditional RCA | AI-Assisted RCA |
|---|---|---|
| Similar-event search | Keyword search and investigator memory | Semantic retrieval across QMS records |
| Fishbone support | Manual brainstorming | Evidence-based prompts by category |
| 5 Why quality | Depends on investigator skill | AI can flag unsupported logic |
| Trend detection | Periodic manual review | Continuous pattern detection |
| CAPA alignment | Manual QA review | AI can compare root cause and CAPA language |
| Effectiveness checks | Often narrow and event-specific | Broader recurrence monitoring |
| Bias control | Depends on reviewer challenge | AI can broaden evidence retrieval |
| Main risk | Missed connections | Overreliance on AI conclusions |
| Final decision | Human | Human |

## FAQ: AI-Assisted Root Cause Analysis

### Can AI determine the root cause of a pharmaceutical deviation?

AI can suggest possible causes and retrieve supporting evidence, but it should not independently determine the final root cause. Root cause conclusions require human investigation, SME review, and QA approval.

### What is the best first AI use case for RCA?

Similar-event retrieval is the best first use case. It is practical, valuable, and lower risk than allowing AI to generate final investigation conclusions.

### Can AI help reduce "human error" root causes?

Yes. AI can challenge weak "human error" conclusions by identifying system factors such as unclear SOPs, poor form design, equipment issues, training gaps, workload, recurring patterns, or prior similar events.

### Can AI help with CAPA effectiveness?

Yes. AI can monitor whether similar deviations, complaints, or failures recur after CAPA implementation. QA must still determine whether the CAPA was effective.

### Does AI-assisted RCA require validation?

If AI is used in a GMP investigation system or influences regulated records, validation should be performed based on intended use and risk. Part 11 controls may apply when electronic records and electronic signatures are involved.

### What is the biggest risk?

The biggest risk is accepting an AI-generated conclusion without evidence. AI can produce plausible but incorrect explanations. Every AI suggestion should be source-linked and reviewed by qualified humans.

### Can AI replace fishbone or 5 Why analysis?

No. AI should support traditional RCA tools, not replace them. The best approach is AI-assisted evidence retrieval combined with structured human-led investigation methods.

## Conclusion: AI Can Improve RCA, but QA Must Own the Investigation

AI-assisted root cause analysis has strong potential in pharmaceutical investigations because RCA is evidence-heavy, pattern-heavy, and vulnerable to human bias. AI can help retrieve similar events, detect recurring patterns, challenge weak logic, support CAPA effectiveness review, and make investigations more complete.

But AI should not become the investigator. FDA requires thorough investigation of unexplained discrepancies and batch failures, including extension to other potentially associated batches or

products and written conclusions and follow-up (FDA, 21 CFR 211.192). ICH Q10 expects structured investigations to determine root cause, with effort, formality, and documentation commensurate with risk.

The realistic future is not AI automatically deciding root cause. The realistic future is AI helping investigators see what they might otherwise miss.

For AIforQA.org, this is a powerful cornerstone article because it addresses one of the most common weaknesses in pharmaceutical quality systems: not documenting the deviation, but understanding it deeply enough to prevent it from happening again.

## References


FDA. 21 CFR 211.192 - Production Record Review. Requires production and control records to be reviewed and approved by the Quality Control Unit before batch release or distribution, and requires unexplained discrepancies or batch/component failures to be thoroughly investigated, including potentially associated batches or products, with written conclusions and follow-up. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211/subpart-J/section-211.192

FDA. 21 CFR 211.180 - General Requirements. Establishes record retention and inspection availability requirements and requires written records to be maintained so they can be used for annual evaluation of drug product quality standards. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211/subpart-J/section-211.180

FDA. Guidance for Industry: Quality Systems Approach to Pharmaceutical CGMP Regulations. Discusses quality systems, CAPA, quality risk management, discrepancy investigations, trend analysis, and the importance of documenting investigation conclusions and follow-up. https://www.fda.gov/media/71023/download

ICH. Q10 Pharmaceutical Quality System. Describes CAPA as a pharmaceutical quality system element and states that structured investigation should be used to determine root cause, with effort, formality, and documentation commensurate with risk. https://database.ich.org/sites/default/files/Q10%20Guideline.pdf

ICH. Q9(R1) Quality Risk Management. Provides principles and tools for quality risk management, including root cause analysis, subjectivity management, risk assessment, interdisciplinary teams, and proportionality of effort, formality, and documentation. https://database.ich.org/sites/default/files/ICH_Q9%28R1%29_Guideline_Step4_2023_0126.pdf

FDA. 21 CFR Part 11 - Electronic Records; Electronic Signatures. Establishes requirements for trustworthy electronic records and electronic signatures, including validation, access controls, audit trails, authority checks, record retention, and electronic signature accountability. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11

EMA. Reflection Paper on the Use of Artificial Intelligence in the Medicinal Product Lifecycle. Discusses AI/ML risk-based lifecycle management, context of use, model performance, data integrity, traceability, and manufacturer responsibility for algorithms, models, datasets, and data processing pipelines. https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-use-artificial-intelligence-ai-medicinal-product-lifecycle_en.pdf