

From Process Signals to CMC Decisions

Accelerating Time to Insight with Visual, Connected Analytics

*A purification case study in data consolidation, investigation,
and reusable workflows*

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Statistical Thinking

Can we make it every day, at scale, with predictable quality?

“

The philosophy of process learning and action based on the following fundamental principles:

- All work occurs in a system of interconnected processes,
- Variation exists in all processes, and
- Understanding and reducing variation are keys to success.

”

–ASQ Statistics Division, Glossary and Tables for Statistical Quality Control, Fourth Edition, (Milwaukee, WI: ASQ Quality Press, 2004).

Where CMC statisticians contribute



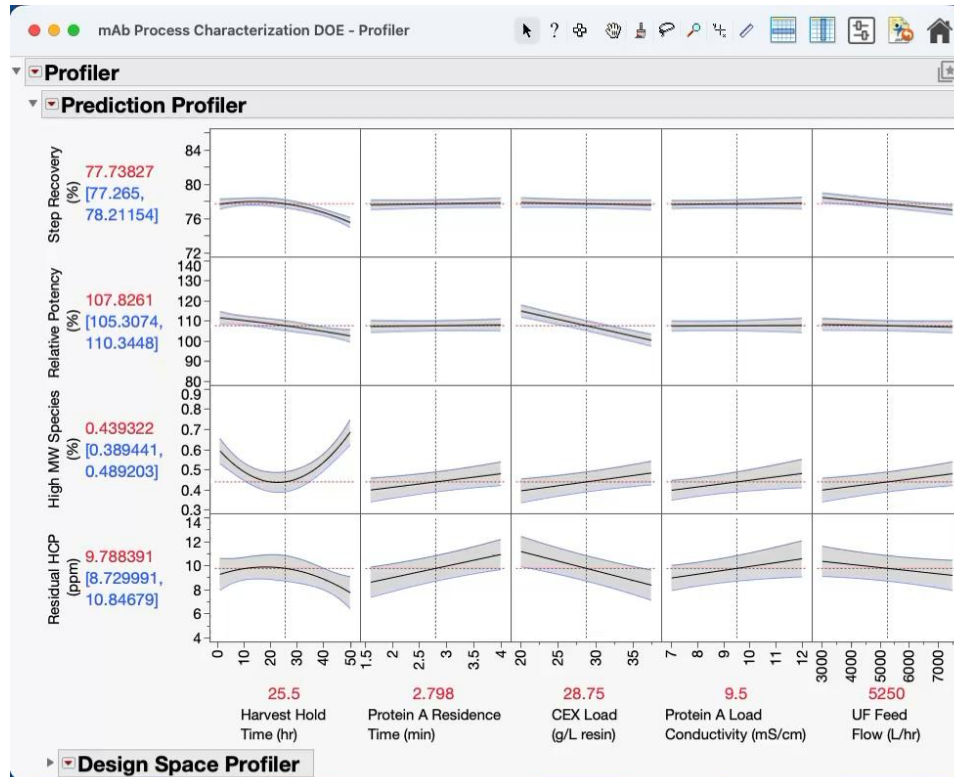
Recurring needs:

- Bring evidence together
- Recognize changes early
- Explain and operationalize decisions

Spooky story:
There was something in the water...

Case study: mAb purification

Tech transfer: Everything is fine



Critical Quality Attributes

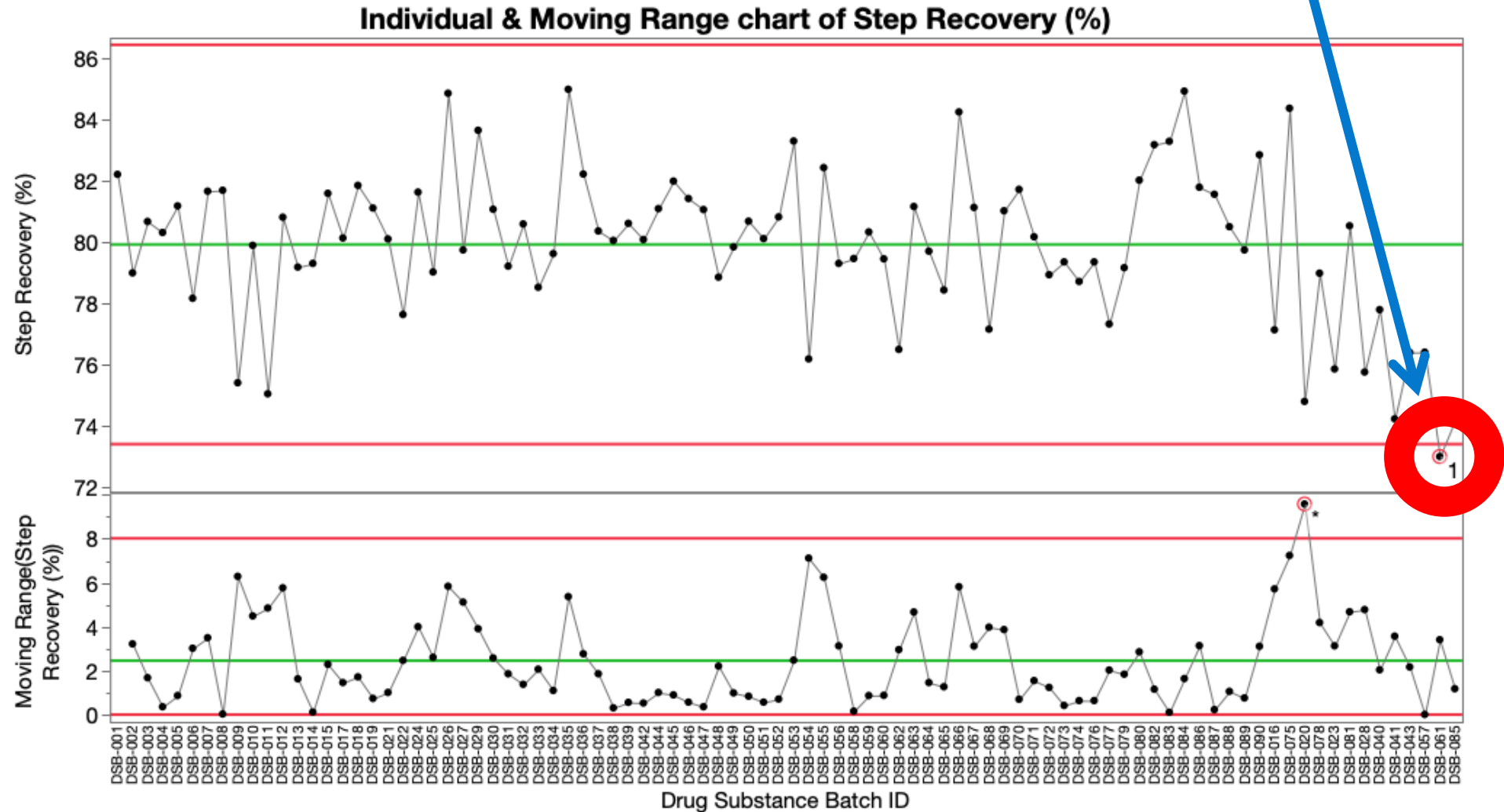
- Step Recovery
- Relative Potency
- High MW Species
- Residual HCP

- ✓ CQA Specification Limits
- ✓ Critical Process Parameters
- ✓ Operating Ranges
- ✓ Interactions
- ✓ Design Space

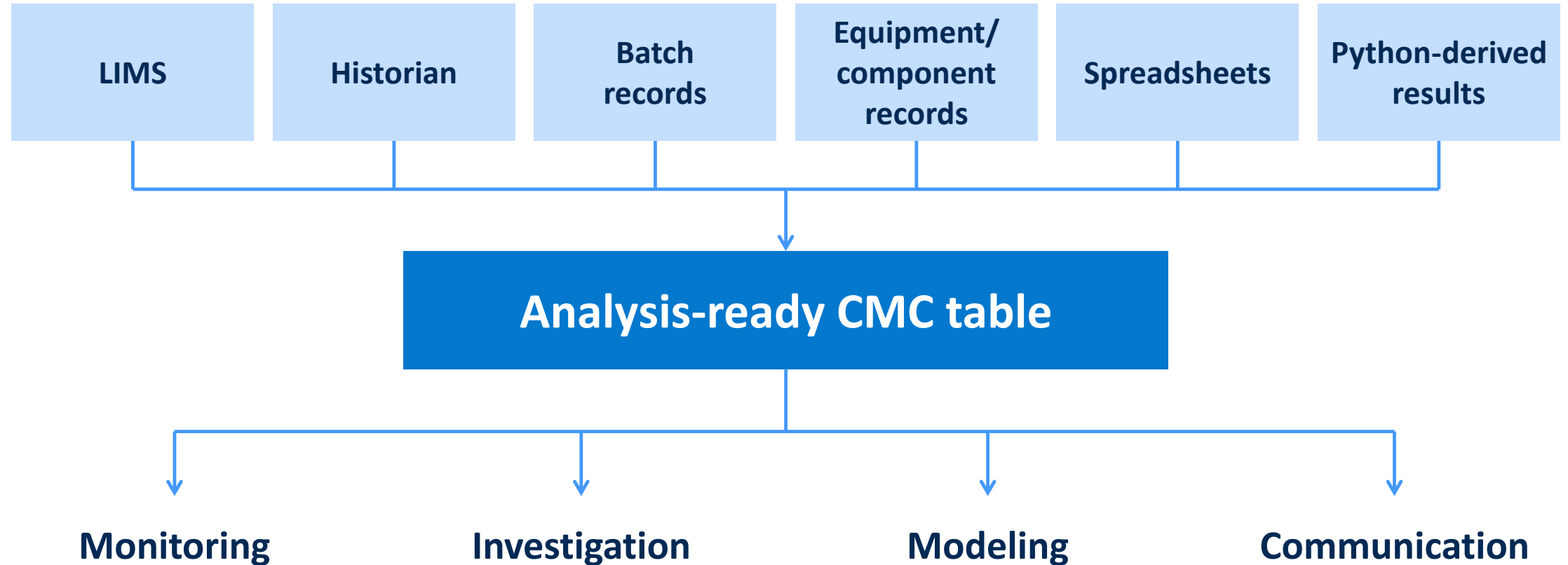
Case study: mAb purification

Current state: Everything is **not** fine

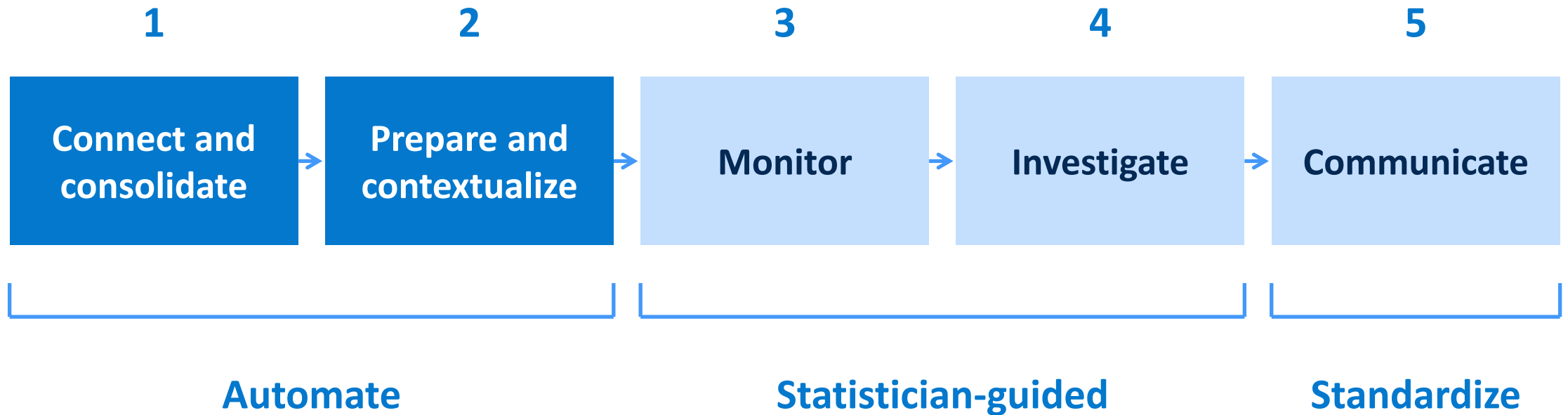
The process is telling us something changed. How quickly can we explain it?



From fragmented sources to an analysis-ready table



Automate the repeatable, preserve the judgement



Workflow demonstration

What was automated? What required expertise?

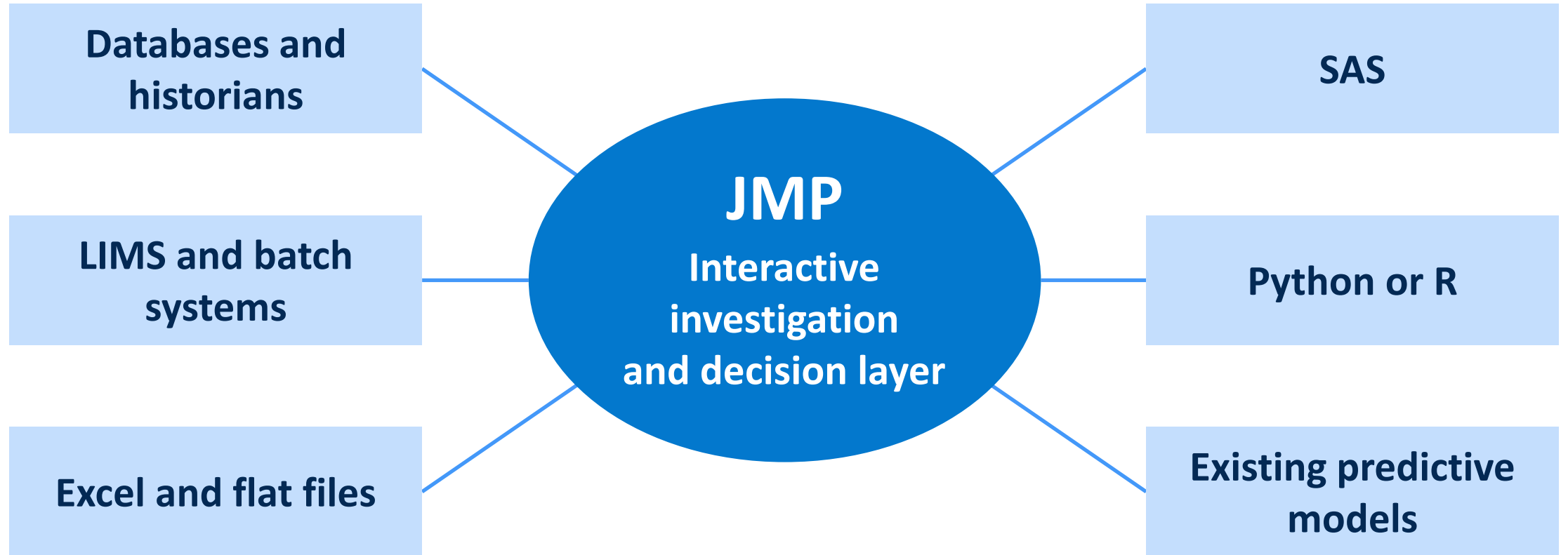
Automated or standardized

- Connecting or importing data
- Joining and reshaping tables
- Creating derived fields
- Refreshing standard monitoring views
- Reproducing approved displays and reports

Statistician-guided

- Evaluating signals
- Choosing a meaningful change point
- Distinguishing association from causation
- Assessing model adequacy
- Recommending confirmation and action

Use all of your tools!



Validated and governed systems remain in place

Conclusion

Before

- Reassemble data for every question
- Move static outputs among tools
- Recreate charts and analyses
- Spend time explaining disconnected results

After

- Refresh an analysis-ready table
- Detect signals across CQAs
- Move interactively from signal to candidate cause
- Explore model-based options visually
- Reuse the investigation as a workflow

Fast

Move from signal to prioritized explanation without repeatedly rebuilding the analysis

Easy

Use dynamic, low-code exploration while retaining statistical control and transparency

Connected

Complement databases, open-source models, spreadsheets, and existing CMC systems