

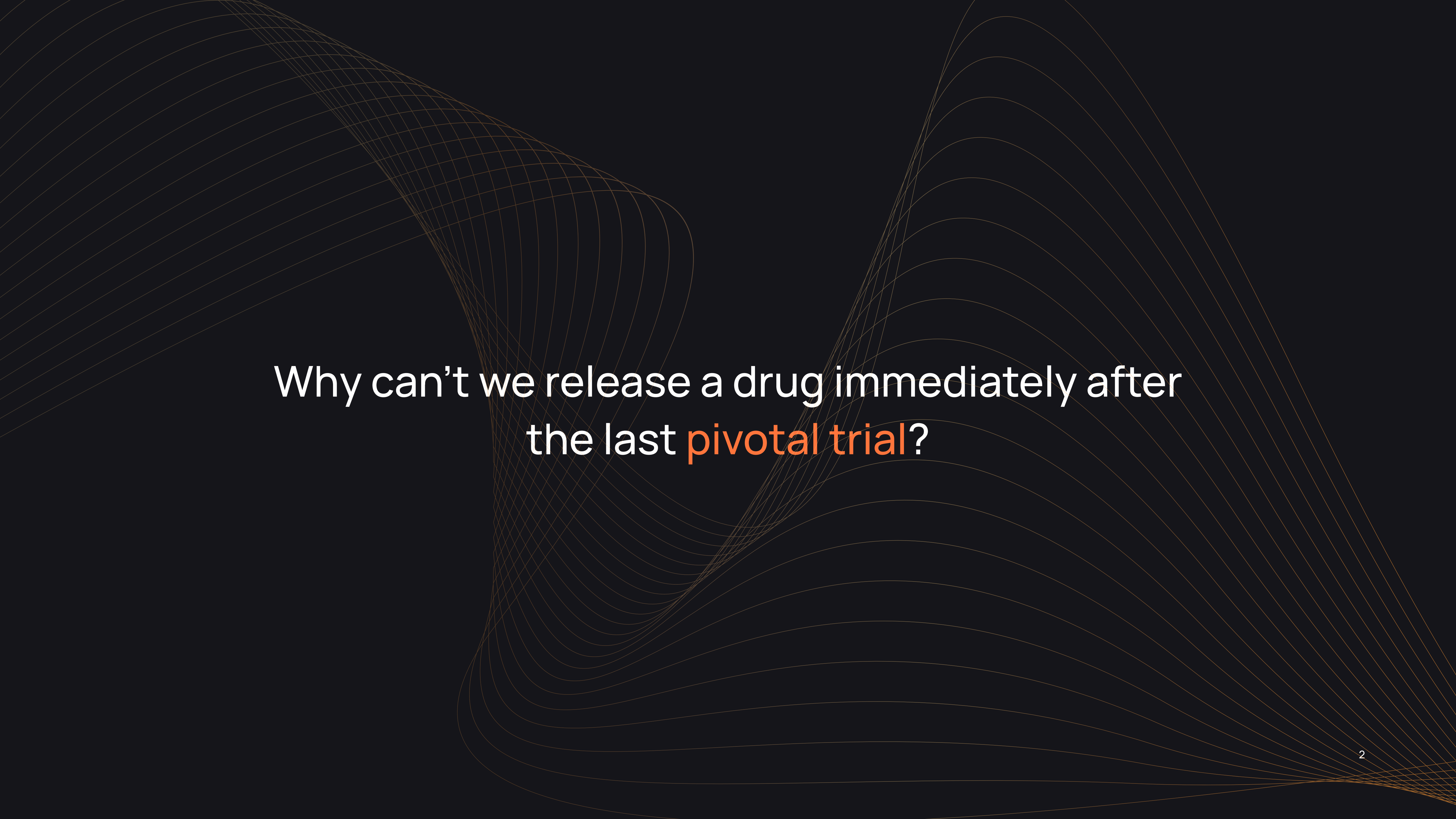


Traceability for Better Understanding, Communication and QC of Trials



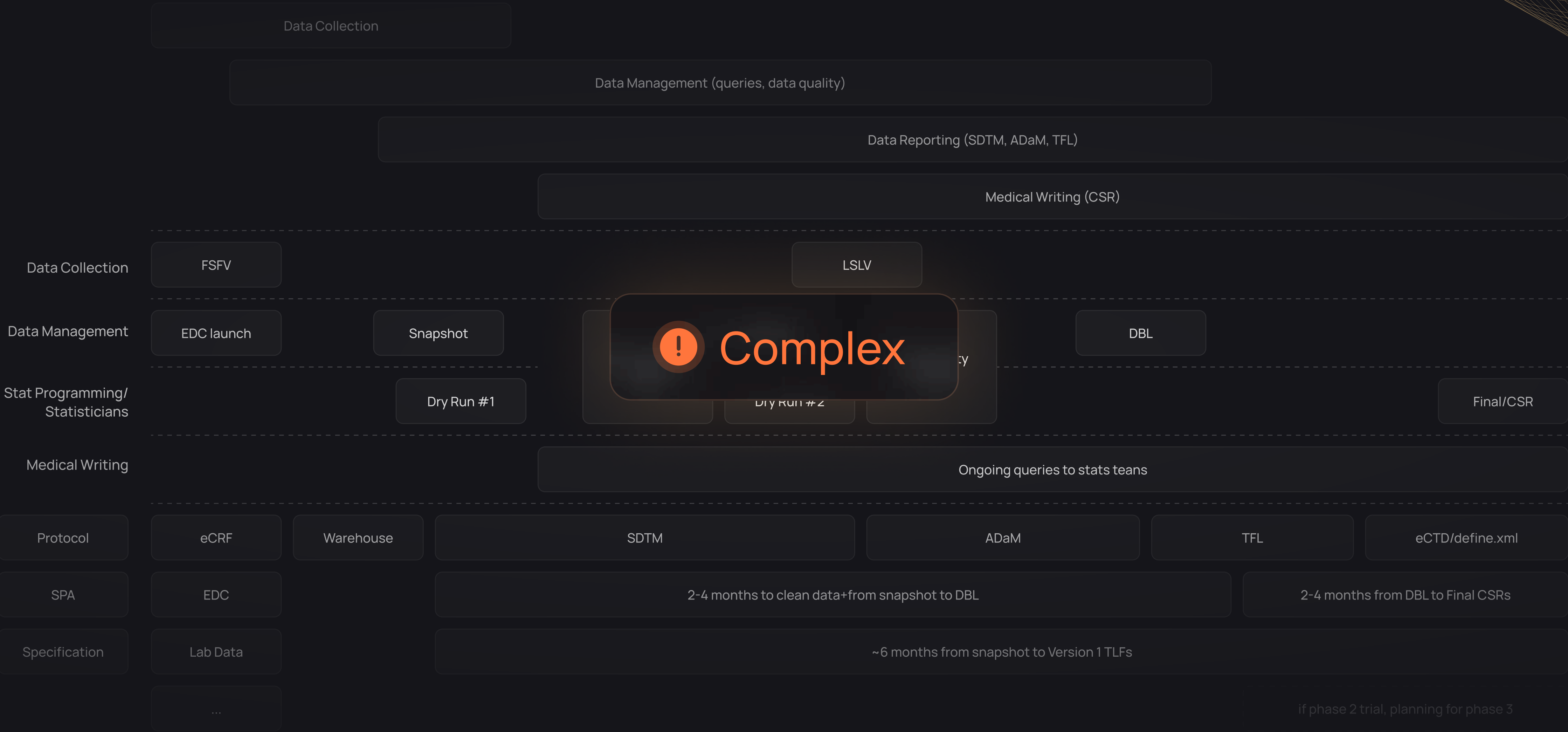
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CEO & Co-Founder, Verisian



Why can't we release a drug immediately after
the last **pivotal trial**?

Drug submission data workflow



What is a valid **clinical trial** analysis?

Valid variable derivations and data

Valid results

Double programming as the gold standard?

Double programming is flawed

Specifications are hard to write and validate

Shared misinterpretations lead to same mistakes

Code sharing undermines independence

Time pressure leads to shortcuts

Work done twice

Computational comparison **fails**

Two wrong programs agreeing...
Doesn't make them **right**

Programmers are stuck

Lack of collaboration
Lack of training

Validation or verification?

CDISC ensures **format**, not meaning

Tools report errors but don't fix them

True **validation** requires **content** transparency

Checking **format** is not checking **content**

The mission

Enhance transparency, communication and quality

Shorter time to market

Lower costs

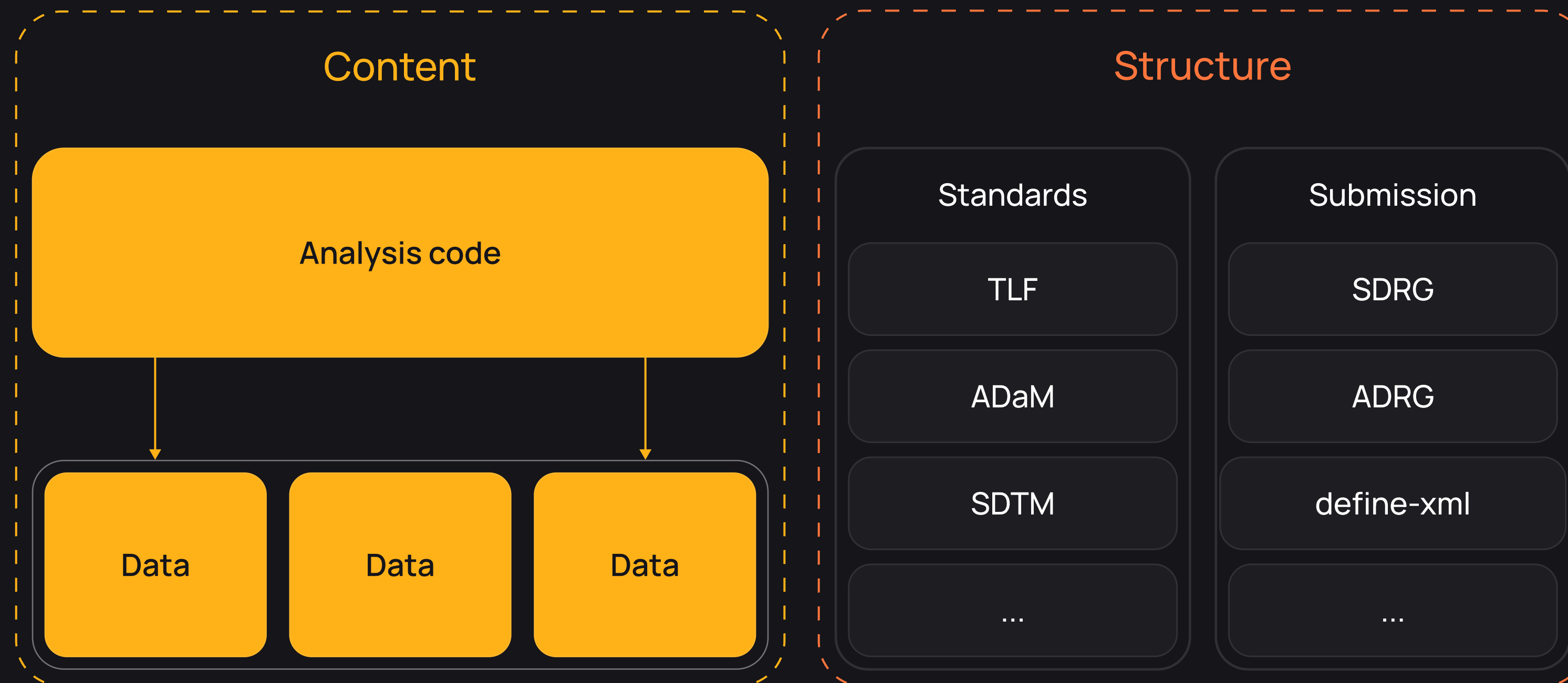
The principles of validation

Seamless integration of protocol, SAP, data, code and submission docs

Full transparency with end-to-end traceability

Constant collaboration and sharing of knowledge across teams

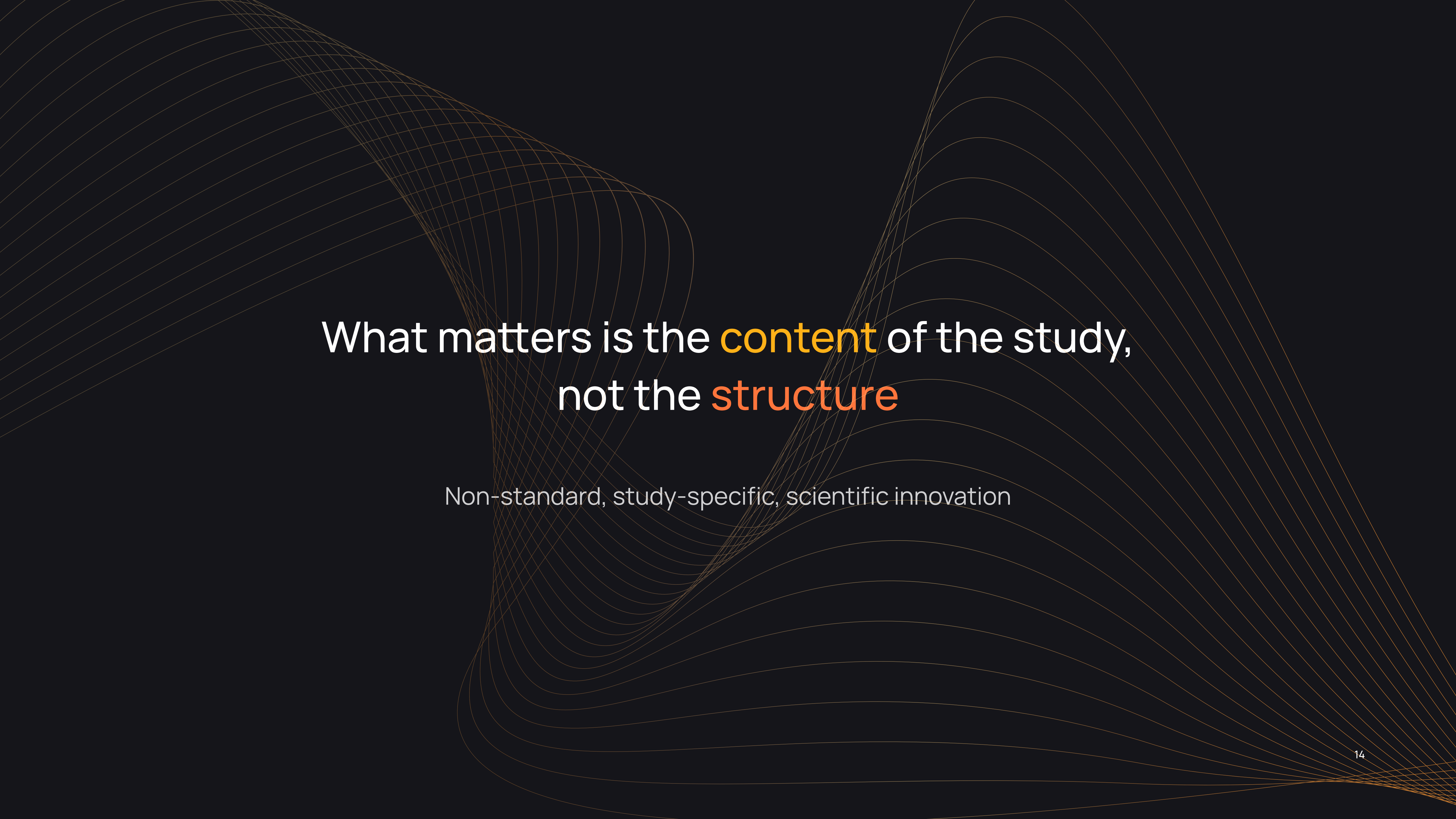
The **source of truth** of **content** of a trial is its code and data



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SAPs, specs, and documents describe what should happen,
but the code shows what **actually** happens

There is no true validation without full transparency



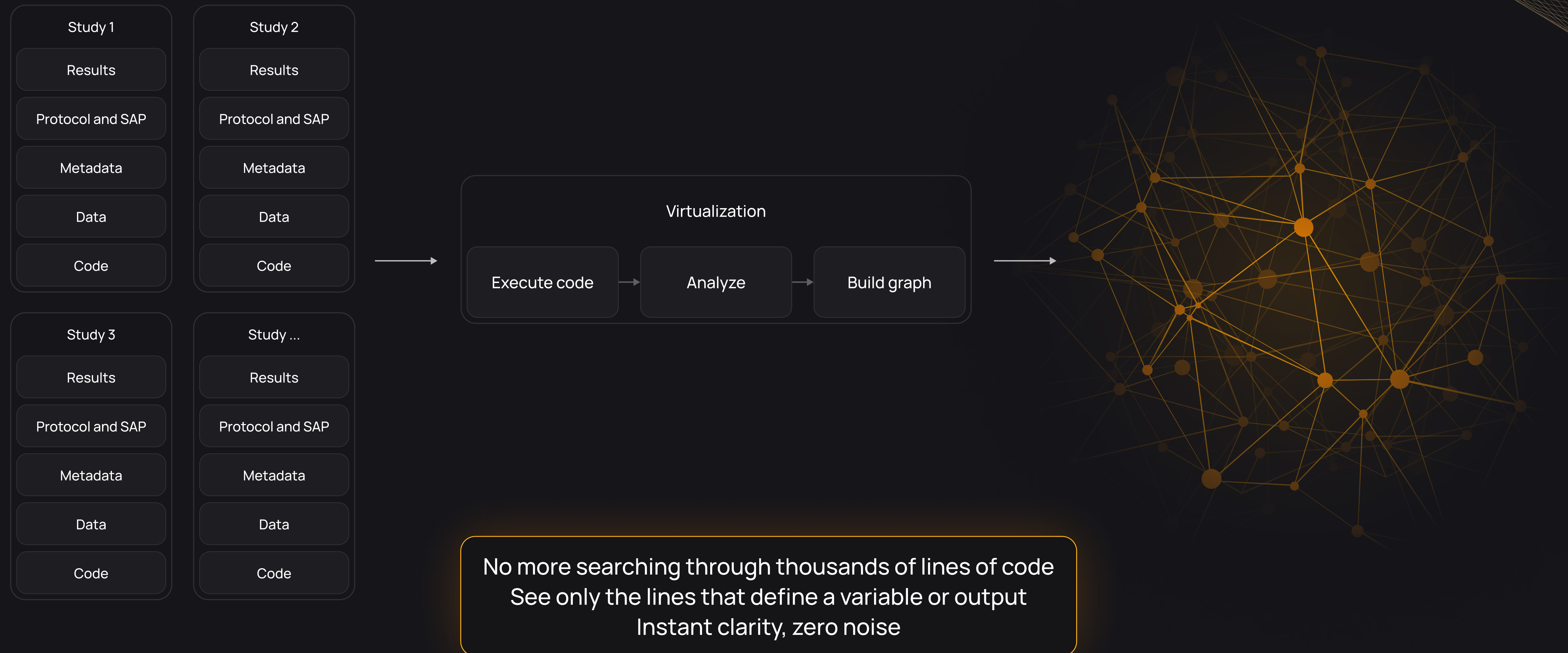
What matters is the **content** of the study,
not the **structure**

Non-standard, study-specific, scientific innovation

Code Traceability changes everything

Tracing the content interactions between data, code and results
Independent of standards and languages

Code Traceability changes everything



Study & patient **traceability**

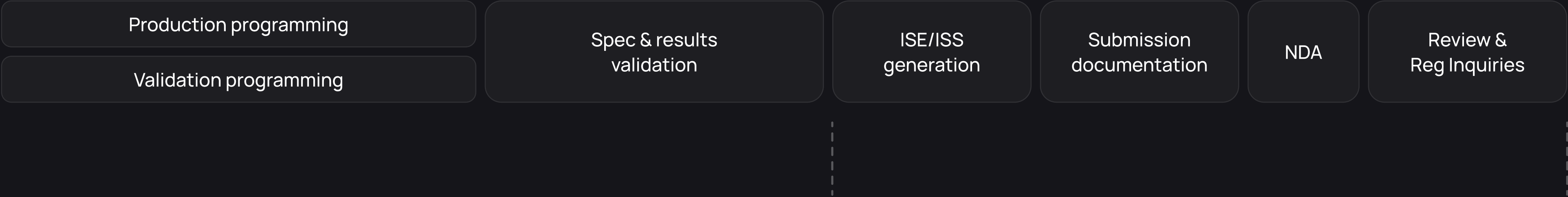
Every transformation from raw data to final results

Find issues in seconds, not weeks

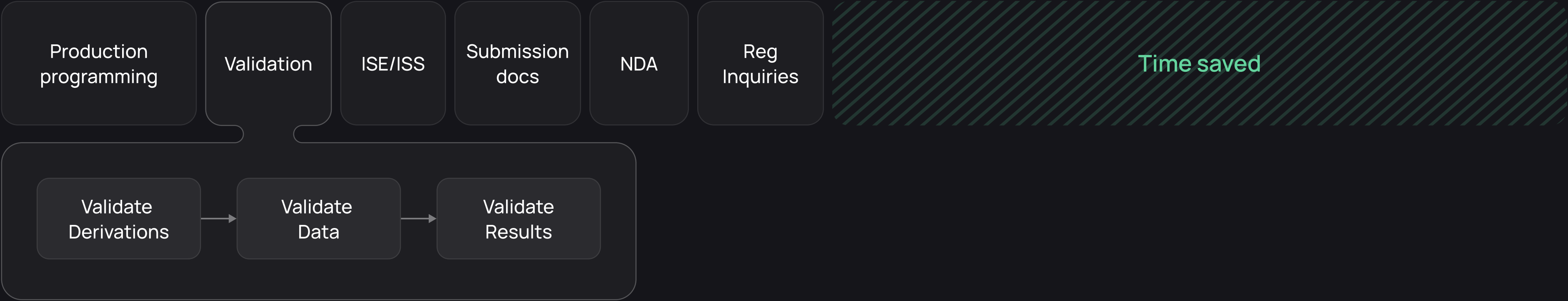
Understand why a patient is included or excluded

The process

Current
Process



Future
Process



Specification **Validation**

Upload specs and scoring with one-click issue tracing
See everything, including code, data, dependencies, impact, specs

Results **Validation**

Instantly trace every output to its source

Identify why a patient is in an output

See everything, including code, data, dependencies, impact, specs

Validation Tracker

Auto-link errors to data and code
No more excel chaos - assign, track, resolve, fast

The Impact

40% reduction in programming effort and cost

80%+ faster root cause analysis

Fewer regulatory inquiries

Accelerated onboarding & knowledge transfer

Greater submission confidence

Augmented submissions

Instantly onboard regulators
Full traceability from raw data to results
Fewer inquiries, faster approvals
Legacy documentation becomes obsolete
Confidence for sponsors, regulators, and patients

Validated by Verisian

