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Traceability and AI for Better Understanding, Communication, and QC of Trials

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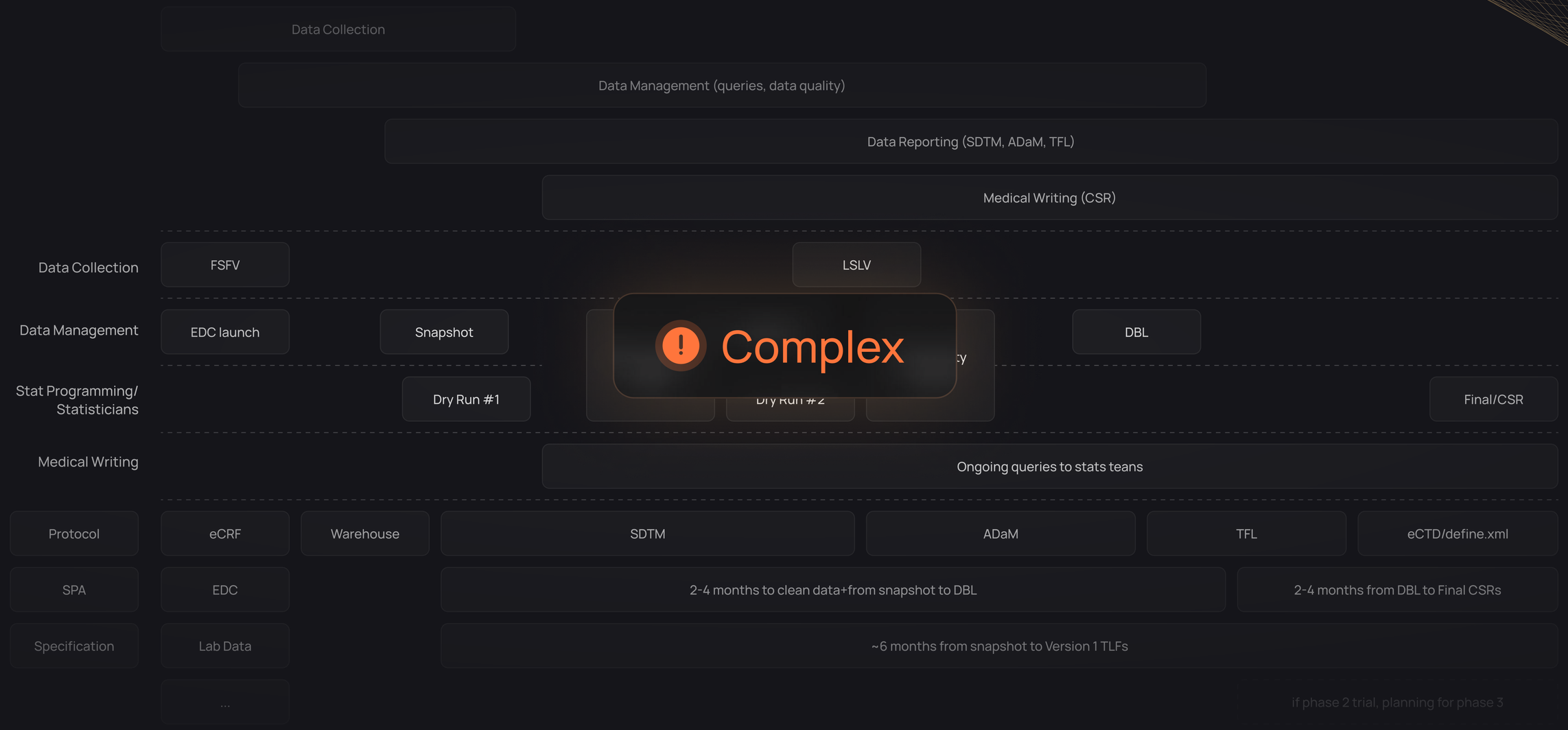
Why can’t we release a drug immediately after the last pivotal trial?

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

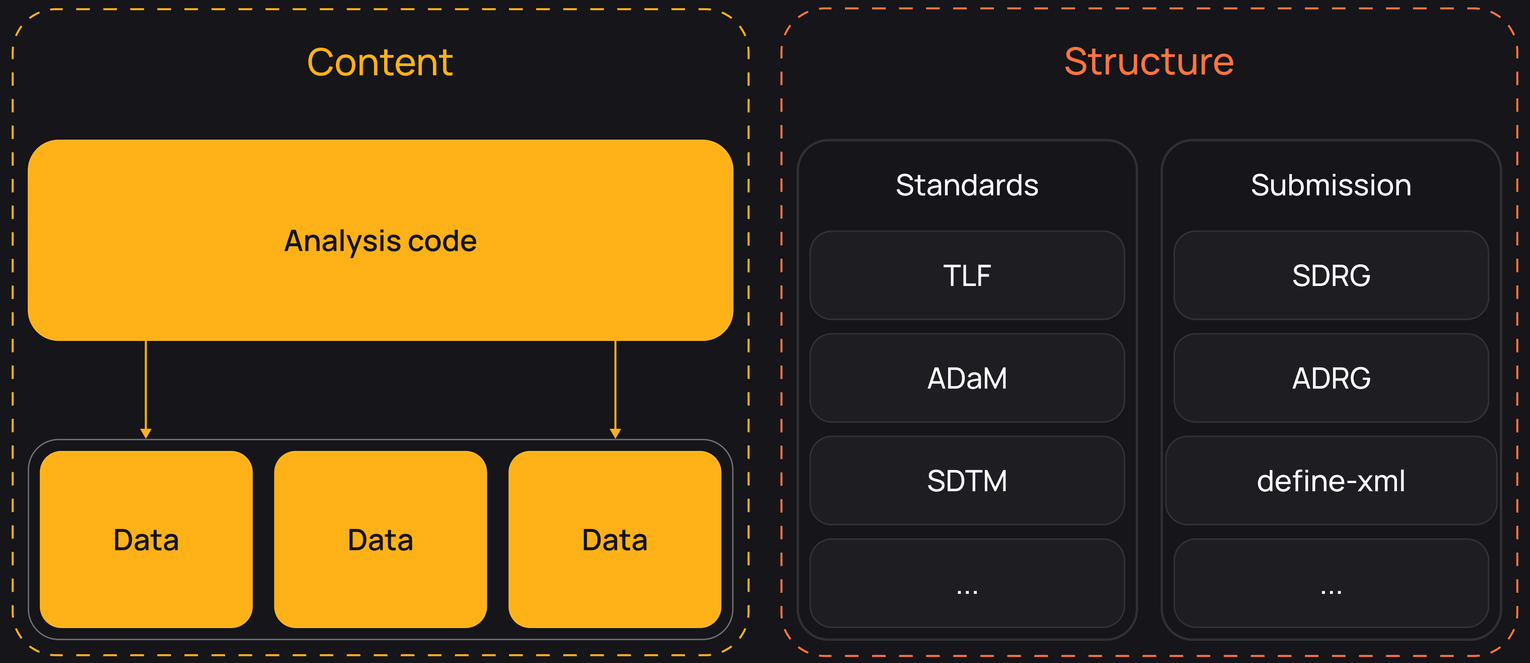
The mission

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



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

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 1	Study 2	Study 3	Study ...
Results	Results	Results	Results
Protocol and SAP	Protocol and SAP	Protocol and SAP	Protocol and SAP
Metadata	Metadata	Metadata	Metadata
Data	Data	Data	Data
Code	Code	Code	Code

→

Virtualization

Execute code → Analyze → Build graph

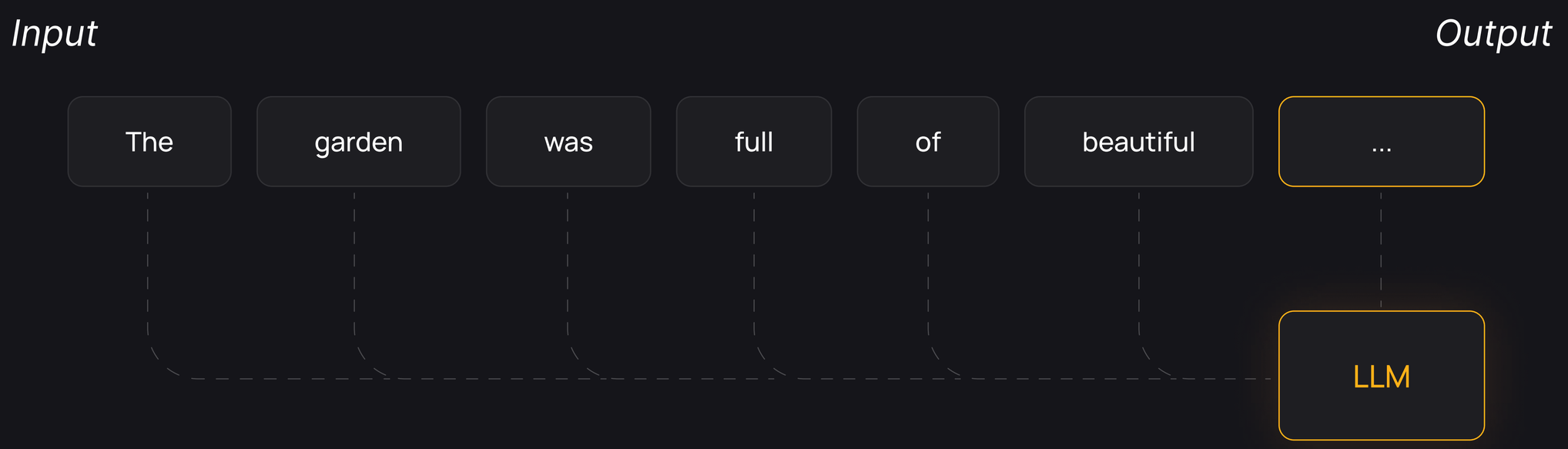
→

No more searching through thousands of lines of code
See only the lines that define a variable or output
Instant clarity, zero noise

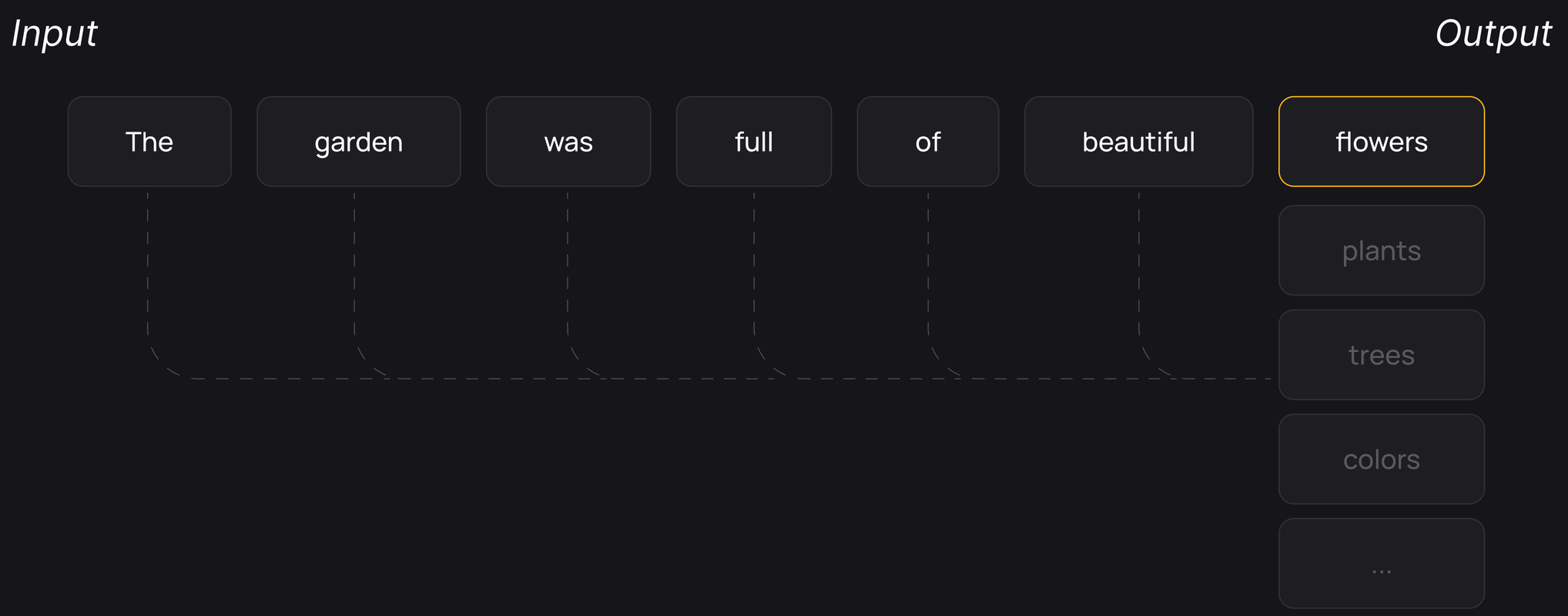
Study & patient traceability

Every transformation from raw data to final results
Find issues in seconds, not weeks
Understand why a patient is included or excluded

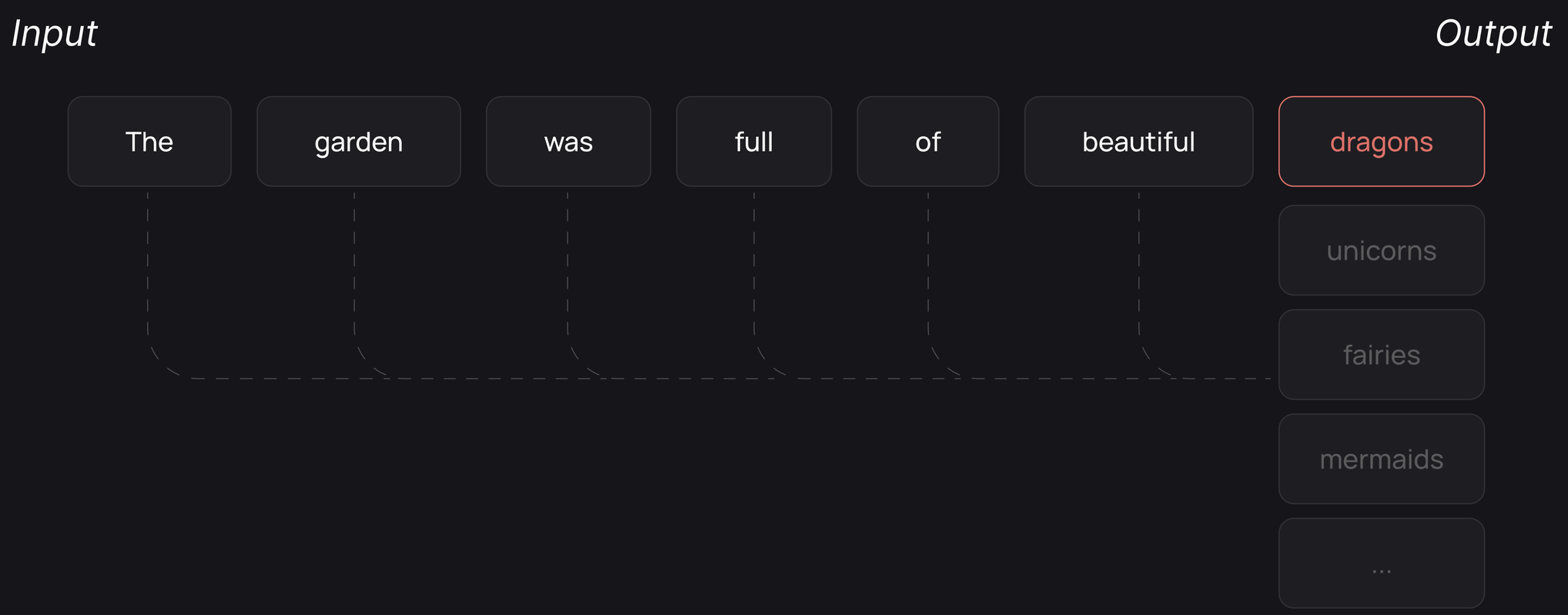
LLMs are really sophisticated autocompletes



LLMs are really sophisticated autocompletes



The bigger the question, the likelier the hallucination



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ORIGINAL PAPER

ChatGPT is bullshit

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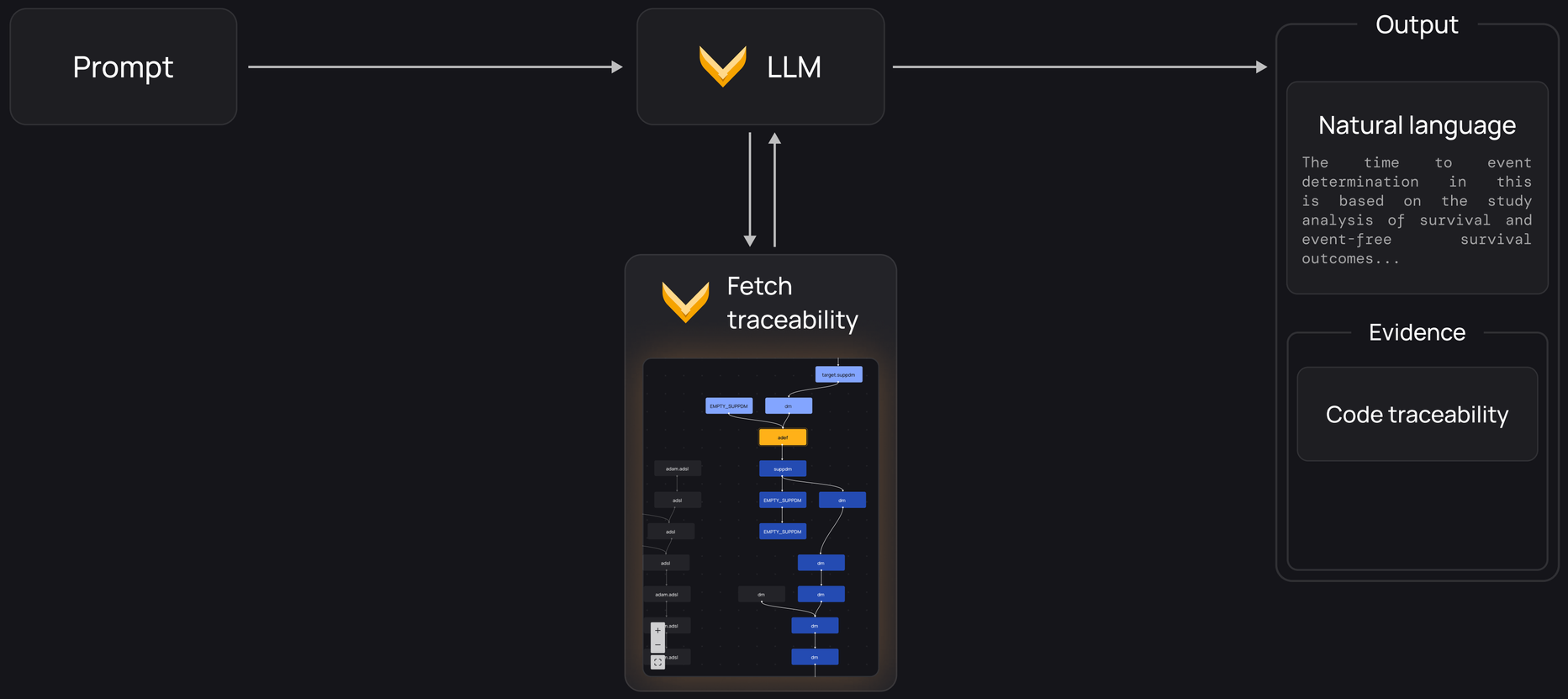
Abstract
Recently, there has been considerable interest in large language models: machine learning systems which produce human-like text and dialogue. Applications of these systems have been plagued by persistent inaccuracies in their output; these are often called "AI hallucinations". We argue that these falsehoods, and the overall activity of large language models, is better understood as *bullshit* in the sense explored by Frankfurt (On Bullshit, Princeton, 2005): the models are in an important way indifferent to the truth of their outputs. We distinguish two ways in which the models can be said to be bullshitters, and argue that they clearly meet at least one of these definitions. We further argue that describing AI misrepresentations as bullshit is both a more useful and more accurate way of predicting and discussing the behaviour of these systems.

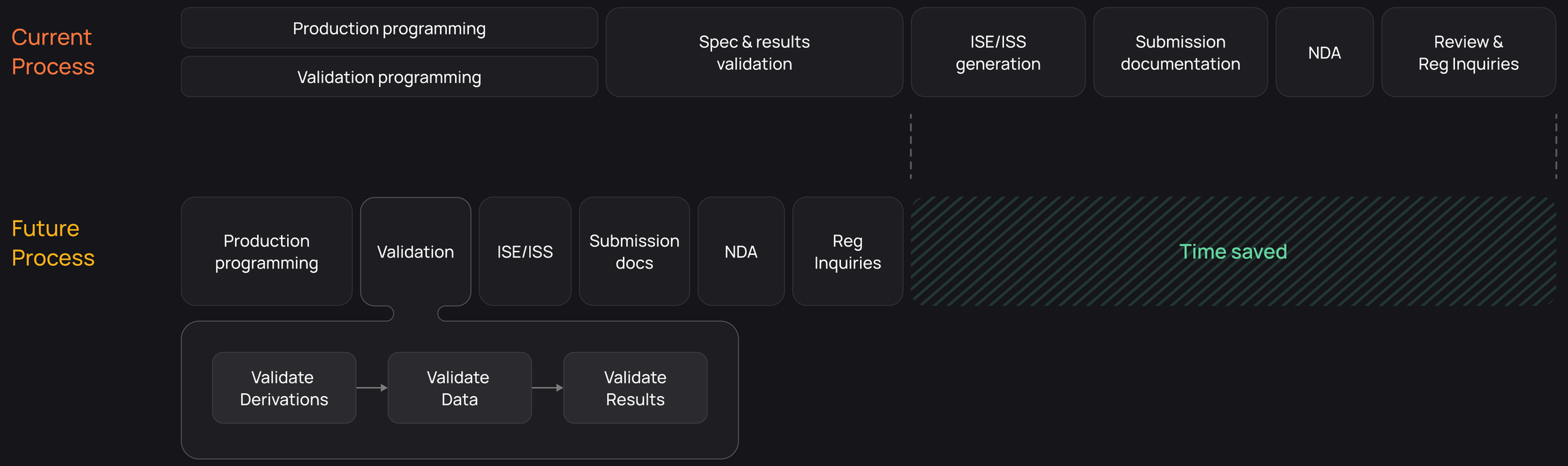
Keywords Artificial intelligence · Large language models · LLMs · ChatGPT · Bullshit · Frankfurt · Assertion · Content

So how can we gain confidence in AI?

Evidence-based AI with Code Traceability



The process


Current Process
Production programming
Validation programming
Spec & results validation
ISE/ISS generation
Submission documentation
NDA
Review & Reg Inquiries
Future Process
Production programming
Validation
ISE/ISS
Submission docs
NDA
Reg Inquiries
Time saved
Validate Derivations
Validate Data
Validate Results

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

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