REGULATORY &
COMMUNICATIONS
STRATEGY,
SCIENCE, &
SOLUTIONS

synchrogenix

A **CERTARA** COMPANY

Leveraging Artificial Intelligence to propel Regulatory Writing
25 April 2018

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Director Of Client Services (Technology)

Meeting Agenda

- Synchrogenix overview

- Artificial Intelligence (AI) Background & its use within Regulatory writing

- Dispelling myths and skepticism of AI assisted authoring

- Evolution from structured authoring

- AI and complementary technologies

- AI Use cases

  - Patient Narratives

  - Transparency & Disclosure

  - Study Reports

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Synchrogenix Overview

Synchrogenix background

Supporting Sponsors For Over 31 years

250+ FULL-TIME Employees WORLDWIDE
Largest regulatory and medical writing group

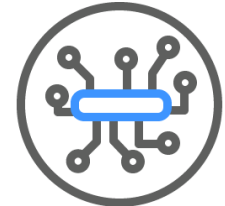**19 Global Locations**

225 EXPERTS IN:

Regulatory strategy

Strategic cross-functional guidance and comprehensive implementation

Submission leadership

GLOBAL HEALTH Authority Experience

Initial and subsequent approvals

Centralized/Decentralized, ROW

TECH enabled SOLUTIONS

GlobalSubmit™
- Regulatory operations technology
- Touched over **95%** of eCTD submissions ever created
- FDA partners **since 2005**

ClinGenuity™
Industry leading
AI-enabled authoring & redaction technology

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End-to-end solution

- Program management
- Global planning
- Due diligence
- Strategic planning and readiness preparation

Consulting

Writing

- Document development and authoring
- Technical editing
- QC/QA
- Niche capability to address clinical pharmacology and Model-Informed Drug Development with scientific writing
- Study level and global filing documents

- Submission management
- Submission compilation
- Document level and submission level publishing
- Document management and maintenance
- Regulatory correspondence

Operations

Transparency & Disclosure

- Clinical trial postings
- Tech-enabled document redaction
- Public disclosure compliance program
- Lay summaries

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Artificial Intelligence (AI) in Regulatory Writing

What is 'AI'?

Natural language processing (NLP) is a field of computer science, artificial intelligence, and linguistics associated with the interactions between computers and human (natural) languages

NLP is related to the area of human-computer interaction

- Many challenges in NLP involve natural language understanding, that is, enabling computers to derive meaning from human or natural language

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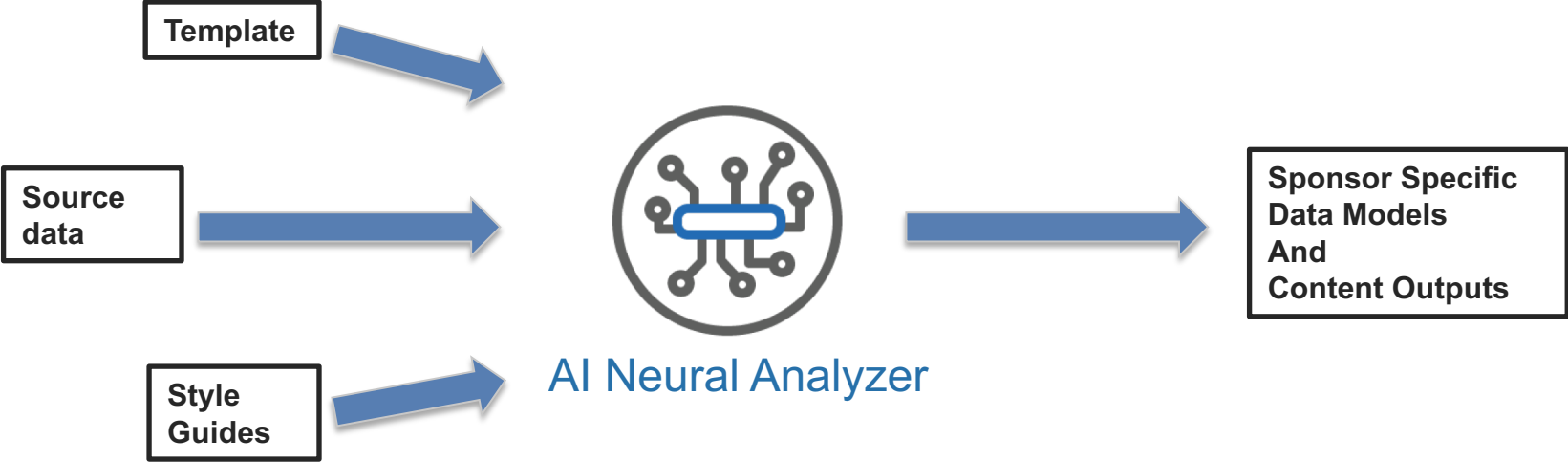
AI Technology background

- A robust Artificial Intelligence Engine can be used for a variety of content re-use and generation

- A System that can identify

  - individual words

  - parts of speech

  - word combinations

  - phrases and phrasing combinations

- Configurable and customizable

- Intelligent enough to analyze previously written content in order to construct an automated process for developing new content based on pre-defined process rules
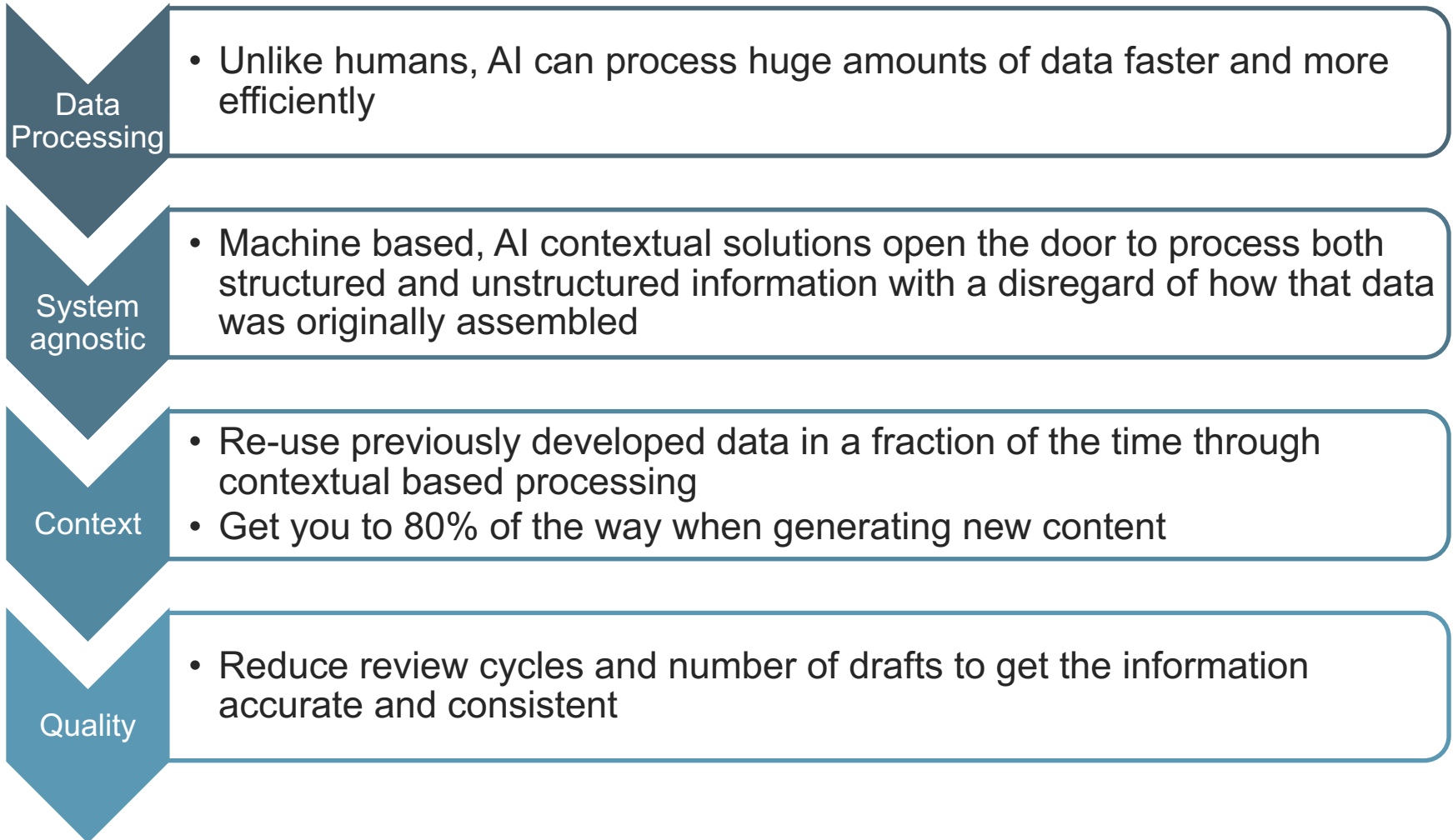
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How does AI authoring work?

Artificial Intelligence uses the past to predict the future

| Template |

| Source data |

AI Neural Analyzer

| Style Guides |

| Sponsor Specific Data Models And Content Outputs |

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Why AI in Regulatory Writing?

- **What are our key goals with this solution?**
    1. Reduce the cycle time to get drug to market
    2. Budgetary challenges - do more with less
    3. Elevate highly skilled scientific resources
    4. Reduce effort spent on quantitative, data-based assertions
    5. Be able to rely on the consistent outputs being generated
    6. Eliminate potential issues that could lead to expensive downstream re-work

- **Key outcomes**
    - Consistent outputs across a whole programme
    - Repeatability and scalability
    - Free up our highly skilled writers to generate scientific insight

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How does AI crunch research time?

Data Processing
- Unlike humans, AI can process huge amounts of data faster and more efficiently

System agnostic
- Machine based, AI contextual solutions open the door to process both structured and unstructured information with a disregard of how that data was originally assembled

Context
- Re-use previously developed data in a fraction of the time through contextual based processing
- Get you to 80% of the way when generating new content

Quality
- Reduce review cycles and number of drafts to get the information accurate and consistent
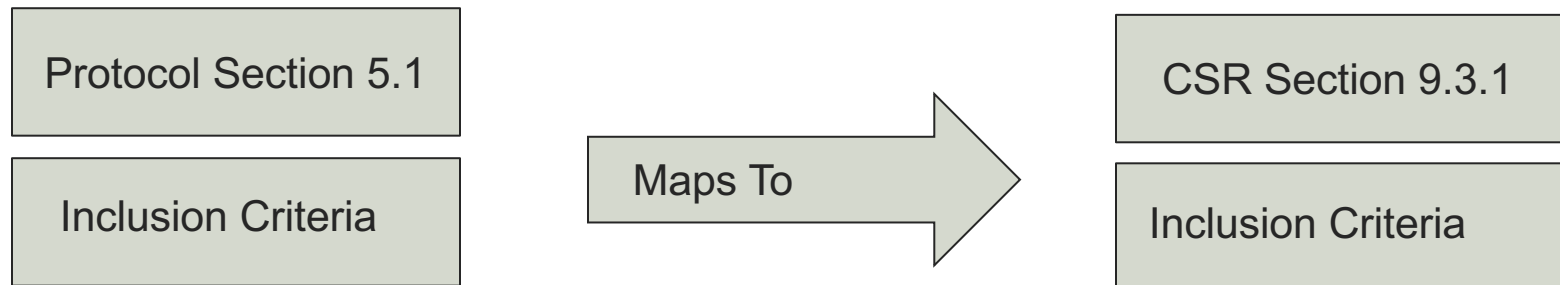
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Evolution from Structured Authoring

How does AI compare with other technical solutions?

- Structured authoring is a publishing workflow in which you use technology to define and enforce a <u>consistent organisation</u> of information in documents

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How does relying on structure work?

- Rigid structure is necessary for the process to work.

- Structures must remain constant and cannot be modified.

- The "System" identifies text by where it exists within the structure, not by the content.

Protocol Section 5.1
Inclusion Criteria

Maps To →

CSR Section 9.3.1
Inclusion Criteria

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What happens when structures fail?

- Pattern matching doesn't work consistently across large organizations or industries.

- Structures fail to remain constant in the R&D universe.

Protocol Section
X   5.2

Inclusion Criteria

Maps To →

??????????????

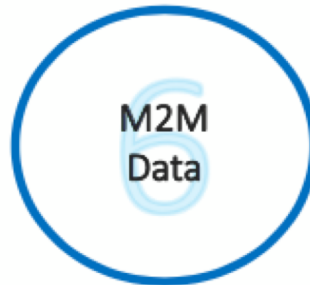**CERTARA**
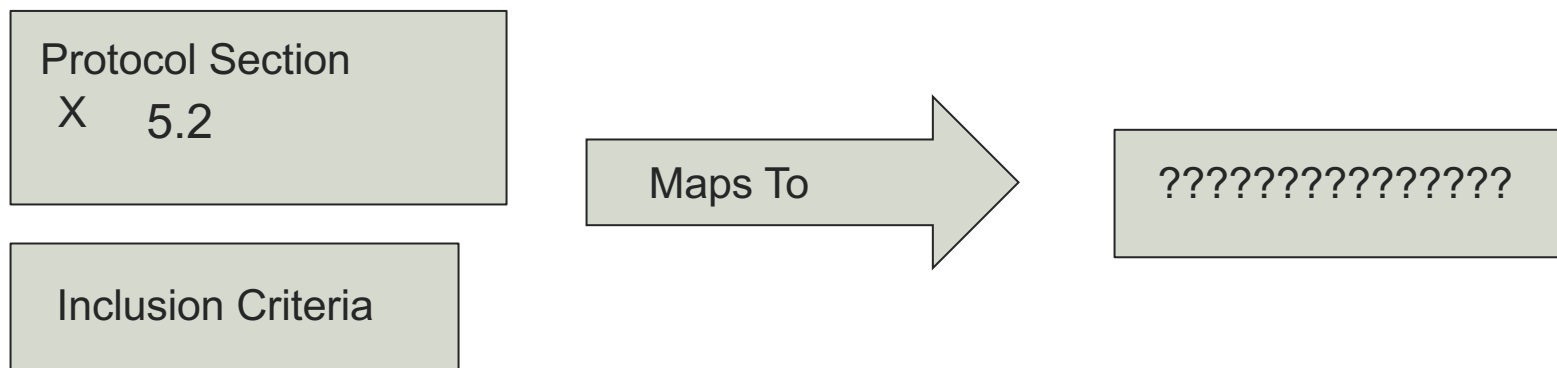
The challenges of structure

- The elements can remain standard, but the structure of those elements often breaks apart

  - Normalized content is achievable (ICH E3).

  - Normalized structure is not achievable

  - Normalized structure is extremely difficult to deploy across an organization.

  - Structured content doesn't manage context

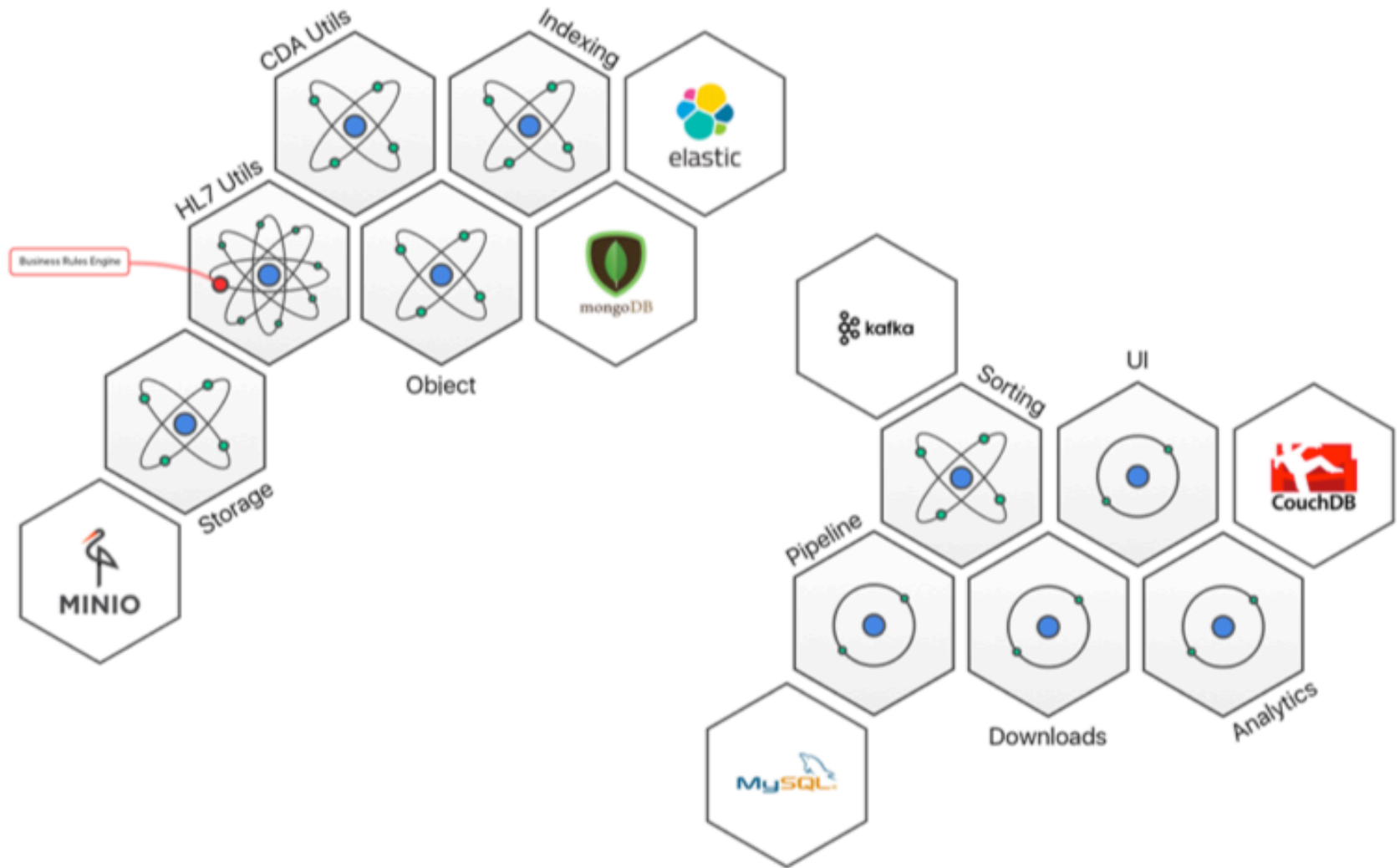 - You cannot create content and normalize without context

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AI and Complementary Technologies

Key elements to successfully re-use information

Identify Data — 1

Desilo Data — 2

Access Data — 3

Overlay Data — 4

Get Data Insight — 5

M2M Data — 6

Data Ownership — 7

Collaborate on Data — 8

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Integrating machine learning with 'Open API' connectivity

Where has Synchrogenix utilized its AI solution?

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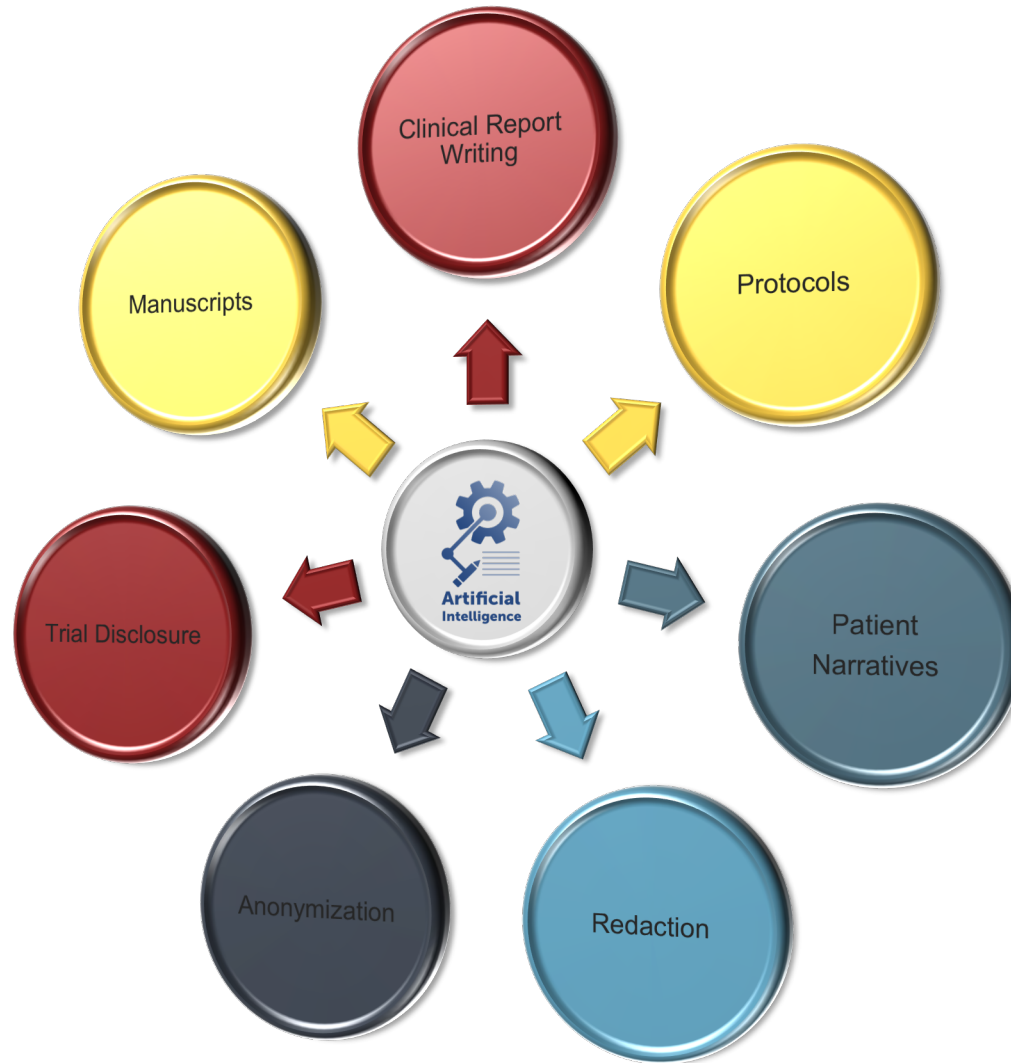
AI Use Cases

AI Use cases – Patient Narratives

- **AI technology compliments and enhances our writing services**

  - Complete end-to-end solution:

Clinical DB Safety DB	→	AI-generated draft	→	Writers confirm flow Limited QC scope	→	Clinical review

  - Risk mitigation

    - Majority of information is pulled directly from the sources. Only manually-edited portions require QC

    - All required elements are always included, critical omissions can be avoided

  - Technology does the heavy lifting

    - Writers to focus on the story and ensure clear, robust, and complete reporting. Clinical review burden is reduced.

    - Burden on programming group eliminated: no need to generate patient profiles/headers/etc.

  - Time and cost savings

    - The AI system can generate up to 1000 narratives an hour that are 80% complete

    - Our full auto narrative generation, writer completion, QC and Clinical review cycle time is typically 500-700 fully completed narratives within 30 days.

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AI Use case – Transparency & Disclosure

ClinicalTrials.gov/EudraCT

- Registering protocols and posting study results to the agency-sponsored websites
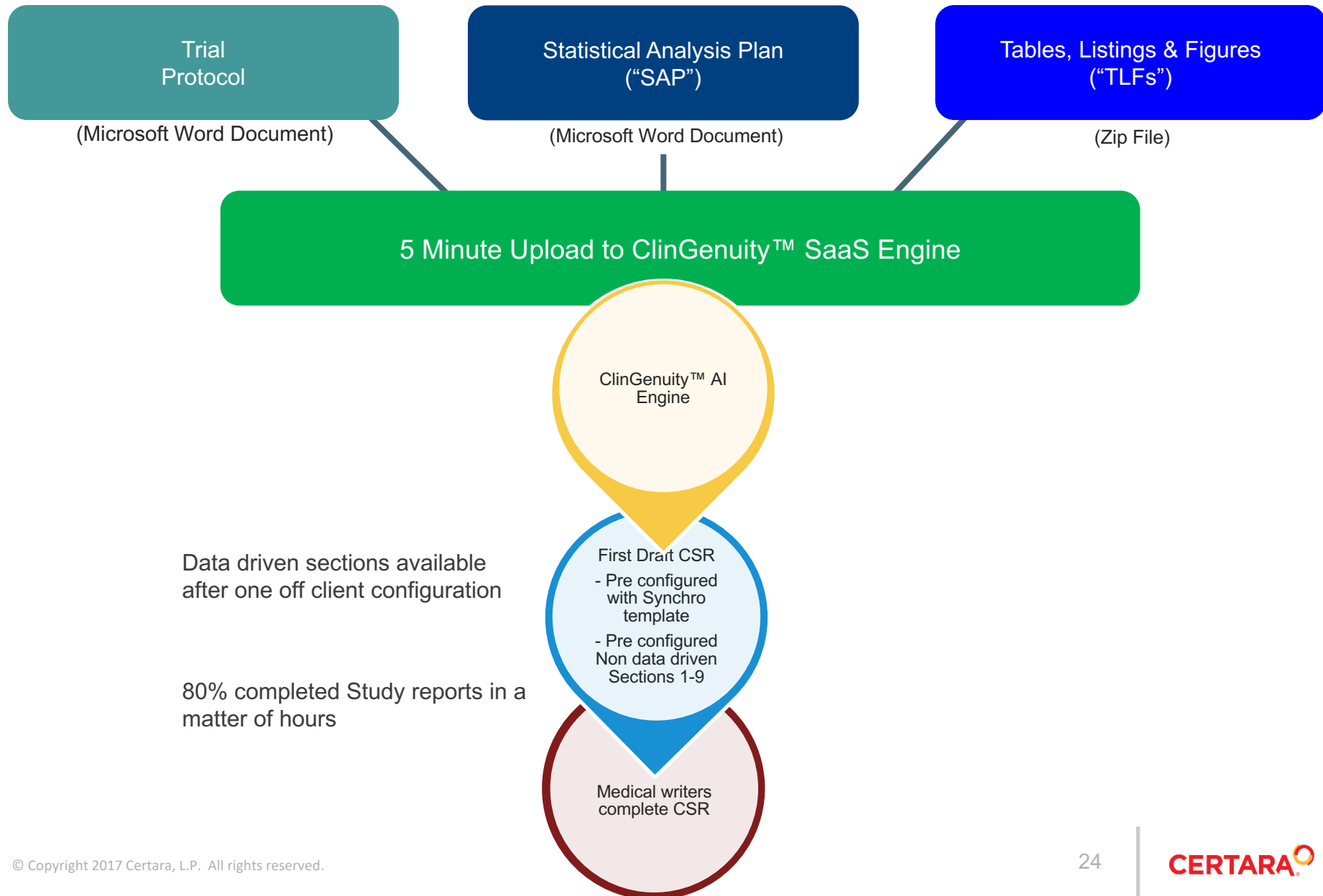
Redaction and Data Anonymization

- EMA Policy 43 and Policy 70

- We offer the only Artificial Intelligence (AI)-enabled redaction solution to automatically identify and redact personally identifiable information (PII), patient protected data (PPD), and company confidential information (CCI)

- > 99% accuracy, 6500 Report redactions, 60+ EMA Pol 70 submissions

Plain Language Summaries

- Provide clinical trial participants with written summaries of their trial's results in non-scientific language (6-8th grade reading and comprehension level)

Clinical trial registration → Redaction → Clinical trial results posting → Lay summaries

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AI Uses cases - Report Writer and how it is working today

Trial Protocol	Statistical Analysis Plan ("SAP")	Tables, Listings & Figures ("TLFs")
(Microsoft Word Document)	(Microsoft Word Document)	(Zip File)

5 Minute Upload to ClinGenuity™ SaaS Engine

ClinGenuity™ AI Engine

Data driven sections available after one off client configuration

First Draft CSR
- Pre configured with Synchro template
- Pre configured Non data driven Sections 1-9

80% completed Study reports in a matter of hours

Medical writers complete CSR

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Questions?