Changing the Face of eTMF with new Technologies

Barry Sacks, Chief Technology Officer

Bring Order, Stability, and Control to Your TMF

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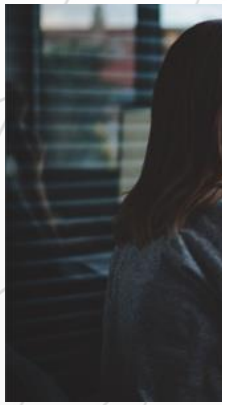
RAISE YOUR STANDARD

TMF TECHNOLOGY

TMF PROCESSING

TMF EXPERT SERVICES

Bring Order, Stability, and Control to your Trial Master File



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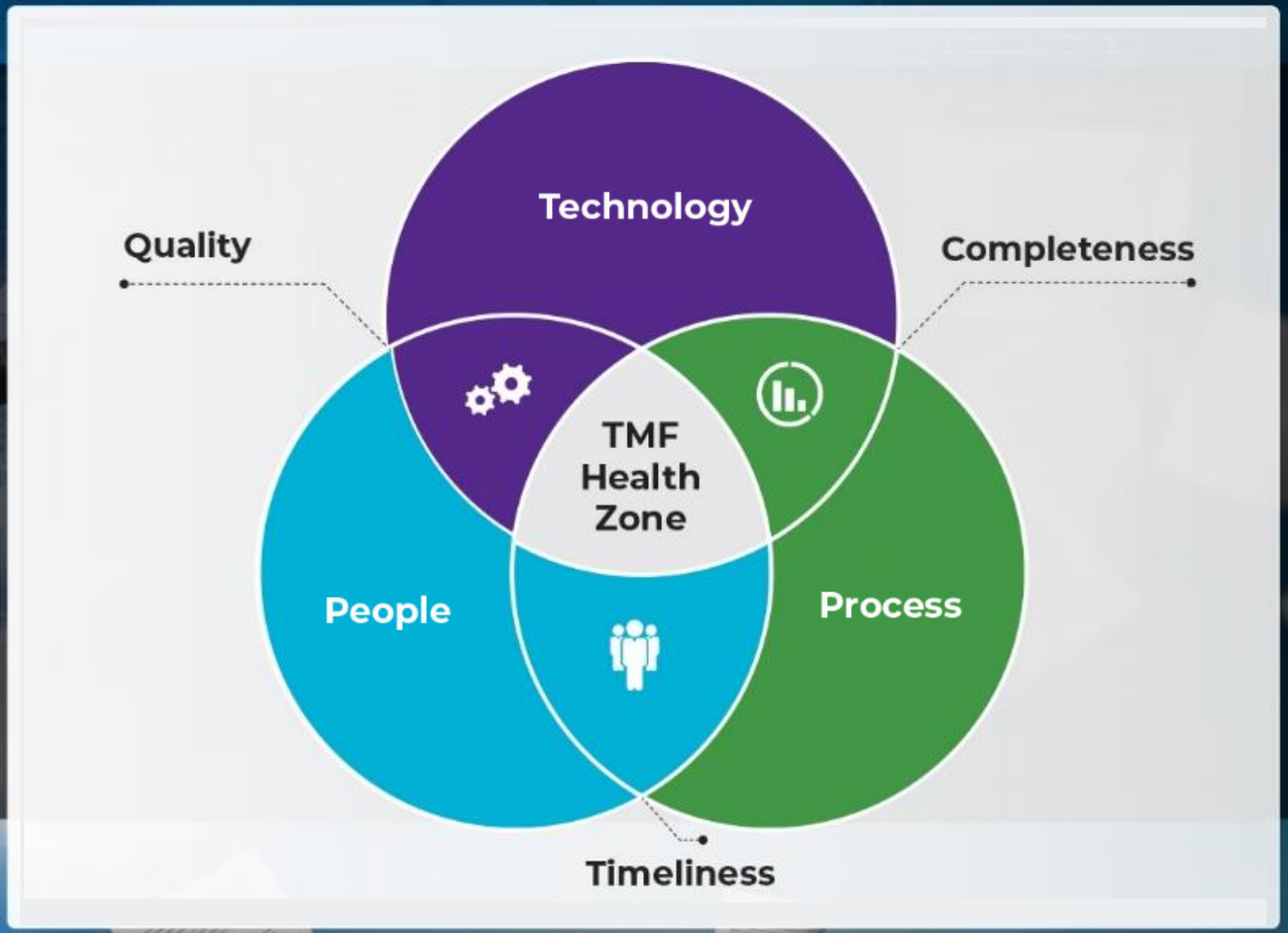
RAISE YOUR STANDARD

PURPOSE-BUILT
eTMF TECHNOLOGY

HIGH-QUALITY
DOCUMENT PROCESSING

EXPERT
TMF SERVICES

Helping you stay in the TMF Healthzone



The right Technology is crucial to maintaining TMF Health

New tools such as AI, ML, ANN, NLP will change the game

Today's Presenter

Barry Sacks

Chief Technology Officer

Barry Sacks is the Chief Technology Officer at Phlexglobal. Barry was previously a Partner within Digital Works Group's Product, Project and Technology team bringing over 25 years of experience leading a variety of start-up, SME and blue-chip organizations through the design, delivery, management and growth of innovative digital products and services. An accomplished technology entrepreneur, corporate director and consultant having worked throughout the UK, Europe, Australia and the US. Prior to Digital Works Group, Barry founded a SaaS venture, was the Global CTO for the FinTech MyJar, the CTO (Corporate Venturing) for Diageo, as well as enjoying a varied interim career.

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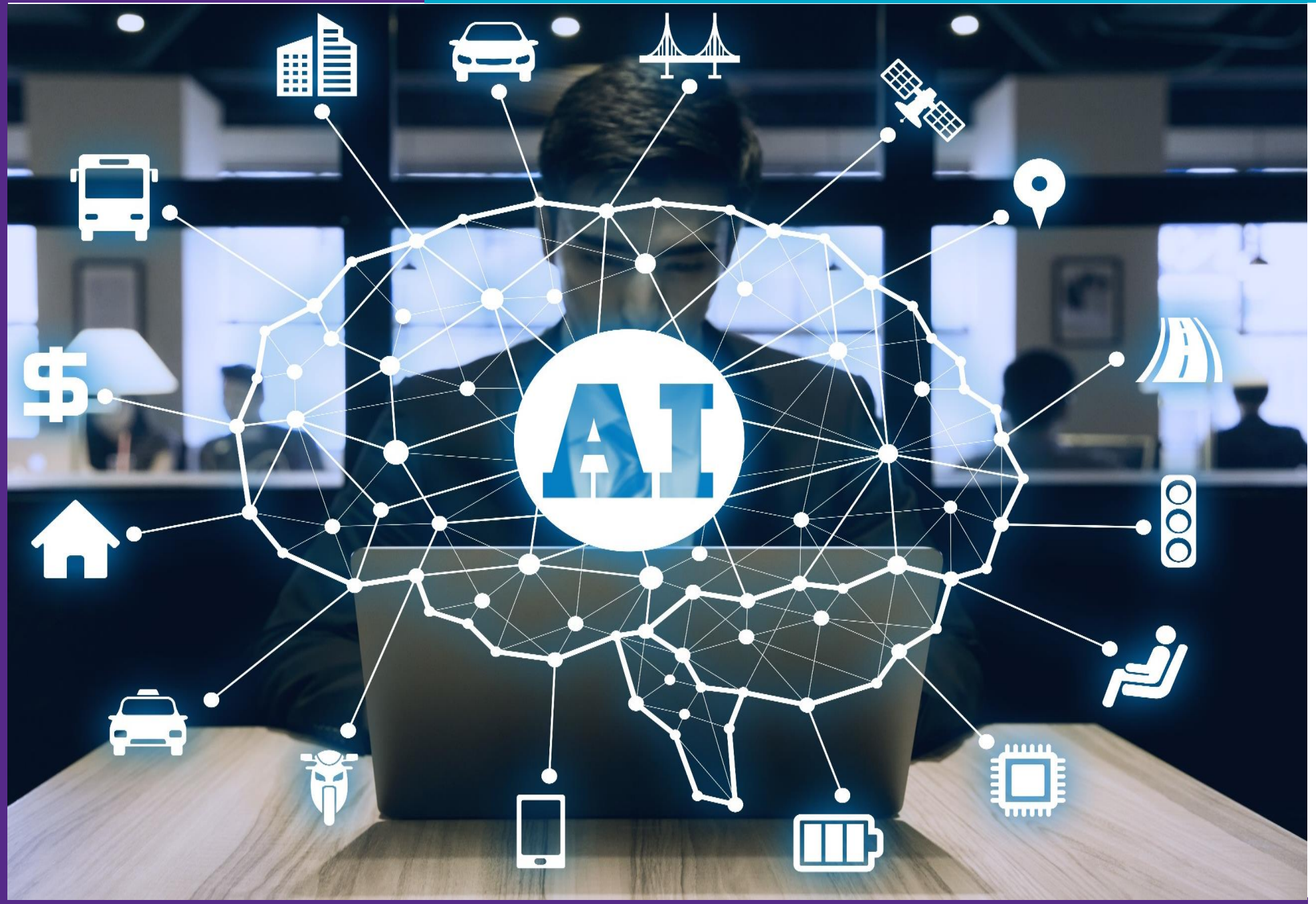

Who is using Artificial Intelligence (AI) today?

AI is already ubiquitous, we are all using it every single day

Larry Elliott – Guardian Newspaper

But there is a lot of Hype surrounding AI

“Robots will take our jobs.

We’d better plan now, before it is too late”

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AI implementation is finally coming of age

But there is still a myth of complexity that creates barriers for adoption

"Everyone talks about it, nobody really knows how to do it, everyone thinks everyone else is doing it, so everyone claims they are doing it."

Dan Ariely - James B. Duke Professor of Psychology and Behavioral Economics at Duke University

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“Gradually then Suddenly” – the evolution of AI

How fast is AI accuracy improving? In fact very fast…

What have these faces got in common?

2014 2015 2016 2017 2019

“Disruptive trends in an industry can rapidly accelerate - leaving the unprepared in the dust”

Marcelo Ballve

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The many fields of AI

Artificial Intelligence contains many subfields, those of interest to us are:

- Machine Learning (ML)
- Artificial Neural Networks (ANN)
- Natural Language Processing (NLP)
- Deep Learning
- Big Data

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ML is the inverse of programming

With ML, computers write their own programs so we don't have to

Traditional software programming:

each algorithm has an input and an output, data goes into the computer, the algorithm executes, and out comes the result.

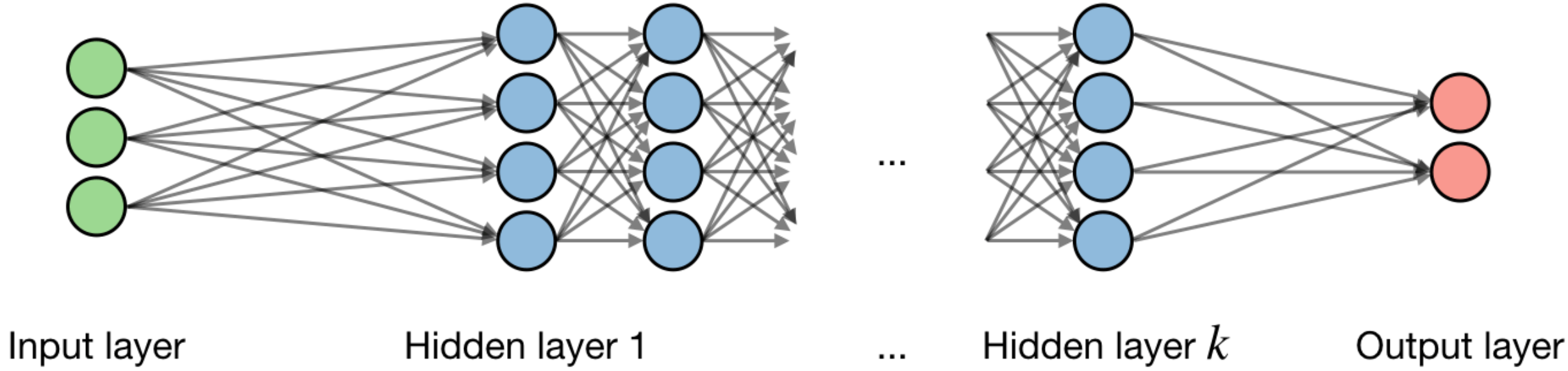
Machine Learning turns this around:

in goes the data and the desired result and out comes the algorithm that turns one into the other.

Learning algorithms are algorithms that make other algorithms.

Artificial Neural Networks (ANN)

ANNs learn without being programmed with any task-specific rules



ANNs with more than one layer are Deep Learning networks

Different layers can perform different kinds of transformations

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Natural Language Processing

Ability for machines to understand and interpret human language

Natural Language Processing is often compared with **text analytics**

Text analytics counts, groups and categorizes words to extract structure and meaning from large volumes of textual content

Natural Language Processing is used to understand the meaning (semantics) and structure of given text data

NLP and text analytics can be used together to extract meaningful information from structured and unstructured content

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Deep Learning

Working with text in eTMF unstructured documents

Linguistic methods for natural language processing required experts in language defining rules to cover specific cases

Statistical methods improve upon classical linguistic methods by learning rules and models from data

Deep learning methods out-compete the statistical methods on challenging unstructured natural language processing problems

With NLP and Deep Learning text extraction and eTMF content classification is now possible through automation

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Big Data and Machine Learning

Large volumes of data are required to train and improve ML accuracy

Training Machine Learning algorithms within Artificial Neural Networks using Natural Language Processing and Deep Learning to classify unstructured content requires lots of **Big Data**

With no data there is nothing from which the machine can learn

With Big Data (large volumes of data) there is lots to learn from

A typical TMF of 2m documents may contain **700 different sub artifacts**

Of these only 3 would individually make up more than **5% of the TMF**

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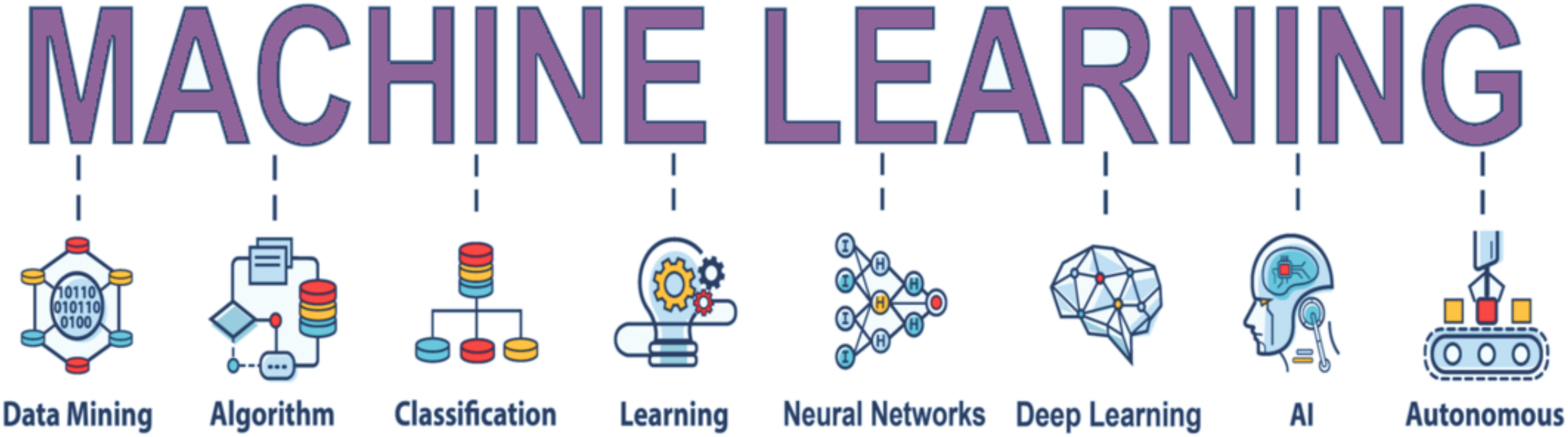
ML now combines nearly all subfields of AI

The term ML is now used interchangeably for computational AI application



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ML in Clinical Trials

Learning algorithms are used extensively in trials (e.g. to determine):

- Where genes are located in a DNA molecule
- Where superfluous bits of RNA get spliced out
- How proteins fold into their characteristic shapes
- How different conditions affect the expression of different genes
- How to weed out molecules likely to have nasty side effects
- Whether drugs they will work so only the most promising get tested
- To avoid expensive failures after human trials have begun

Using AI in an eTMF

How AI technologies are being used in an eTMF today

Using AI to assess TMF content provided by Sponsors and CROs against DIA reference models or Sponsor originated mappings

Scoring completeness, quality and compliance in heatmaps

Enhancing process automation within TMF user workflows

AI assisted document classification, indexing and filing

Improving TMF quality using machine extracted meta-data and automated content classification (with or without user interaction)

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eTMF NLP document Auto-classification

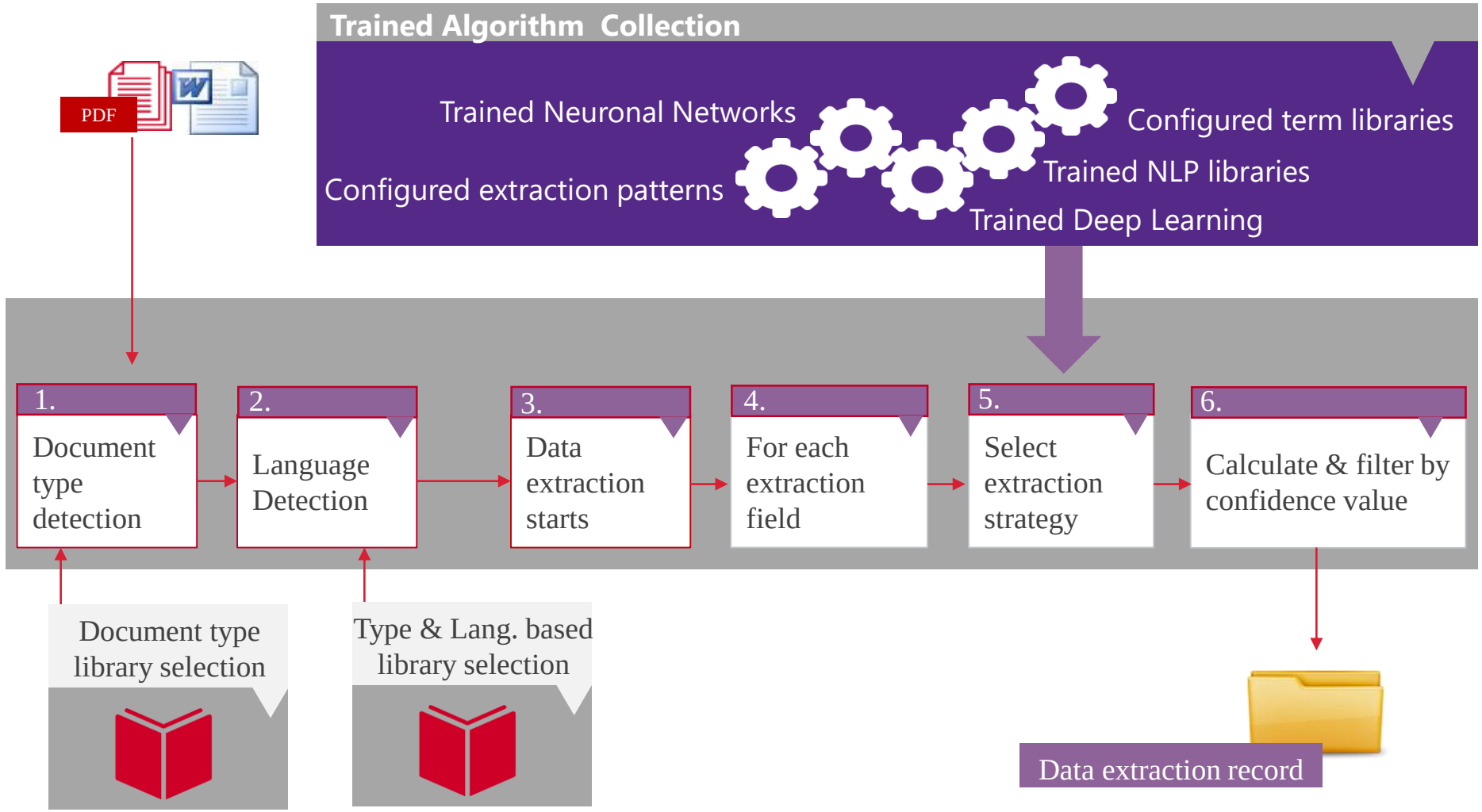
Auto classifying documents within Artifacts and Sub-artifacts

10,000 unclassified documents

Manual processing ~21 days

Autoclassification reduced effort by 70%

Study processed in ~6.5 days



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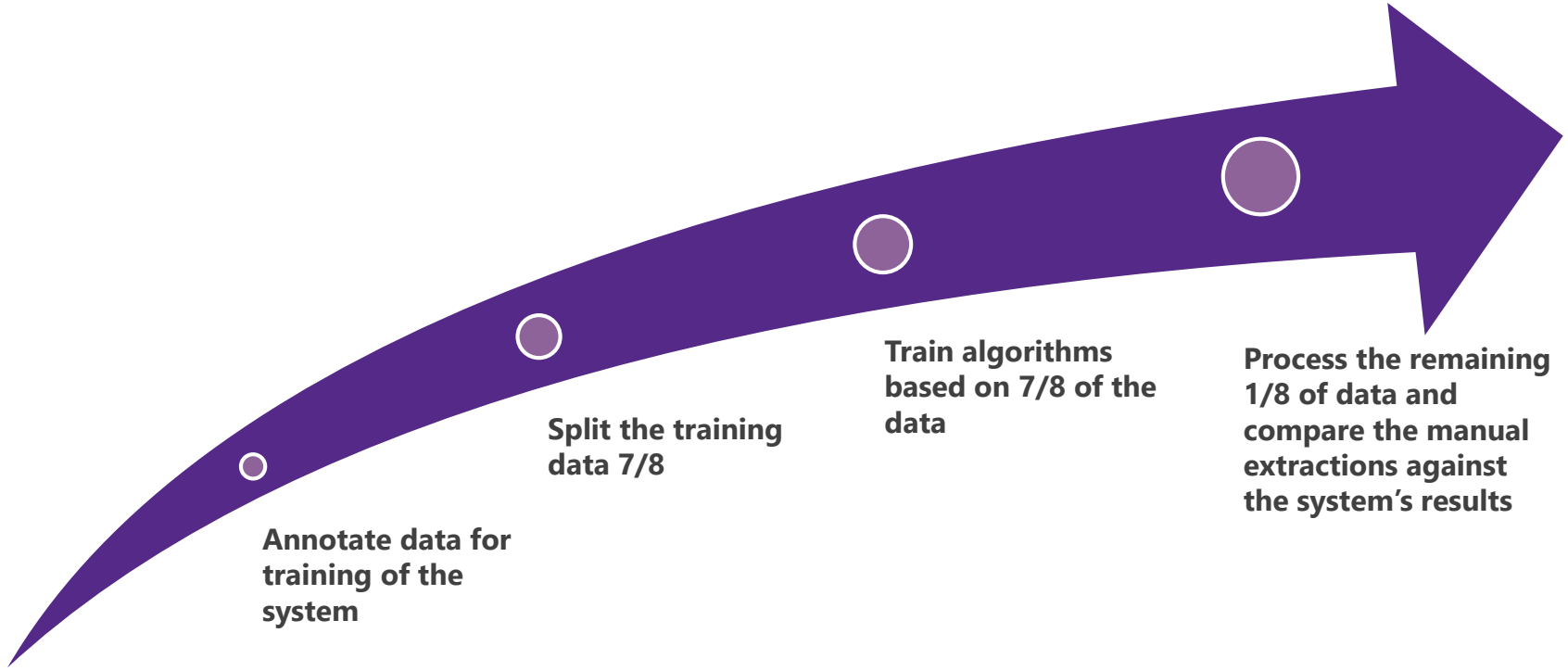
eTMF NLP document Auto-indexing

Automated data indexing via data mining of multiple document types

- 10,000 unclassified documents
- Manual indexing & QC ~4 mins per document
- Autoclassification and text extraction reduced overall effort by 50%
- Average document QCd in ~2 mins



- Protocol number extracted from SVR ~80% accuracy
- Physicians name extracted from CV (first & last name) ~70% accuracy

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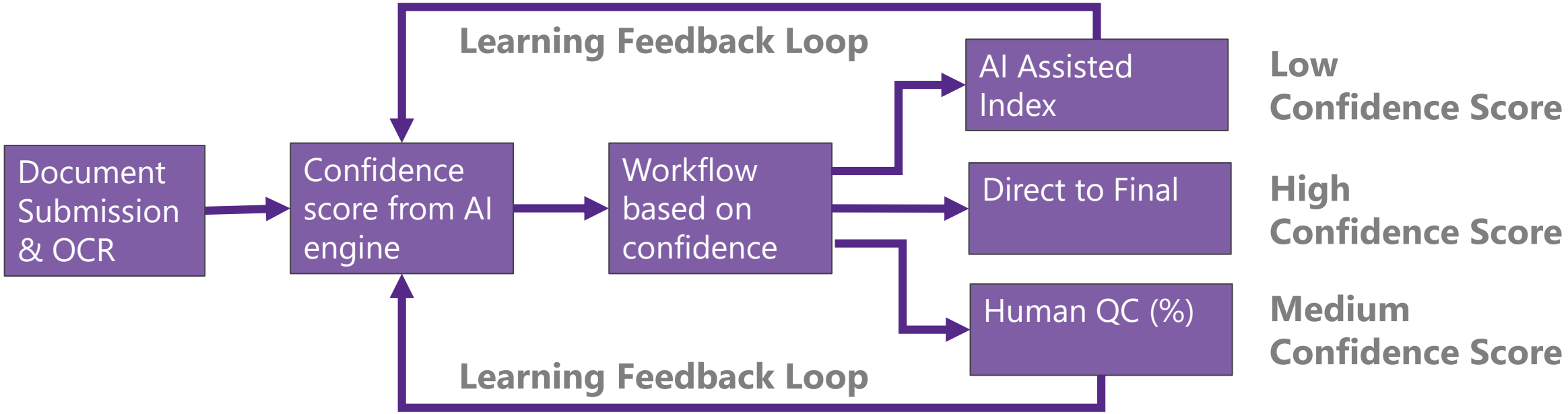
AI will impact current eTMF processes

Increased confidence (and accepted regulation) will allow full automation



Artifacts with **high confidence** once proven can be fully **AI indexed**
Artifacts with **medium confidence** can be AI indexed with **human QC**
Artifacts with **low confidence** can be indexed manually with **AI Assistance**

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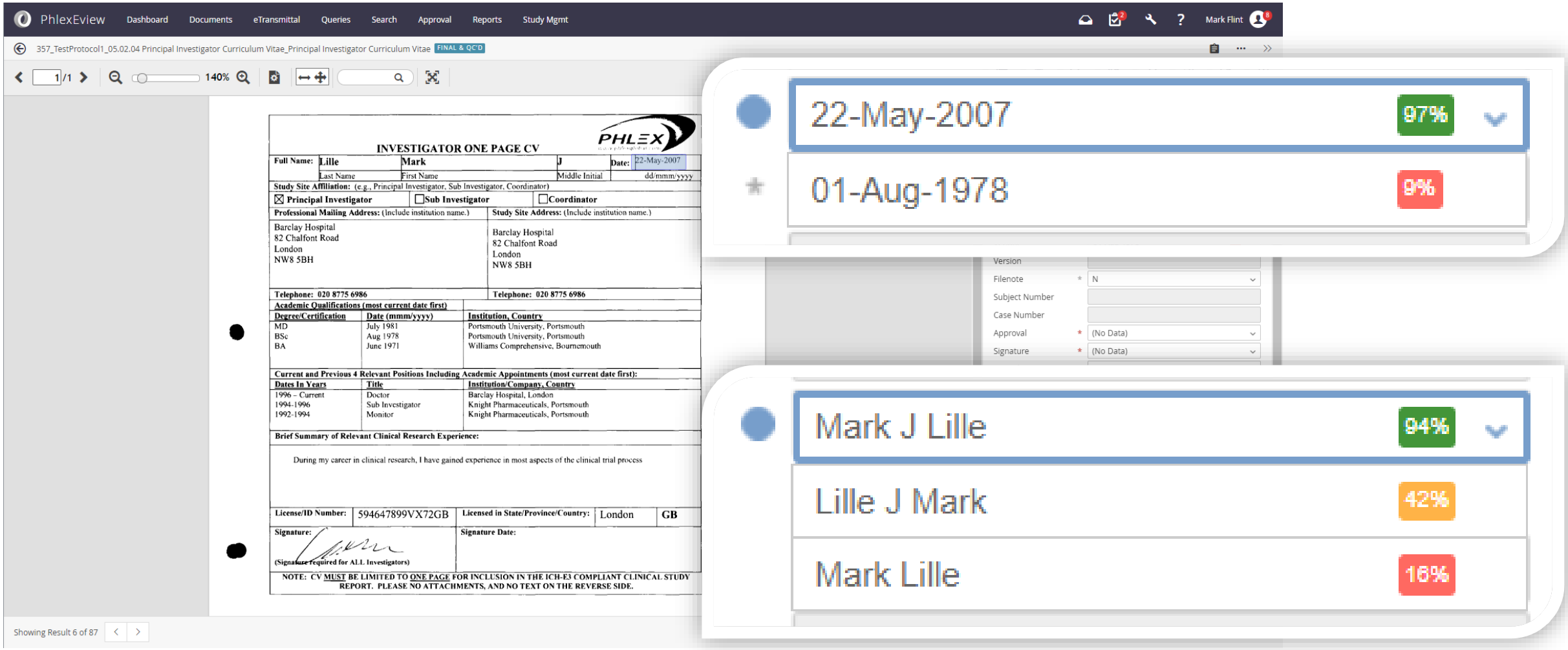
AI Assisted Indexing on document submission

AI will move low-value manual input effort to high-value QC effort



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The future for AI based technologies in eTMF

Opportunities exist to further extend the use of AI technologies in eTMF

Moving from retrospective reporting to predictive analytics

Simplifying distributed/mobile submission processes through automated filing

Using the “power of the crowd” to predict TMF quality issues before they occur

Using AI confidence scores to direct skilled resources to known risk areas

Higher value resource contributions to assessing eTMF quality and accuracy, compliance and risk

Integration of other emerging technologies e.g. Blockchain to validate content chain of custody across the entire clinical trial lifecycle (not just within eTMF)

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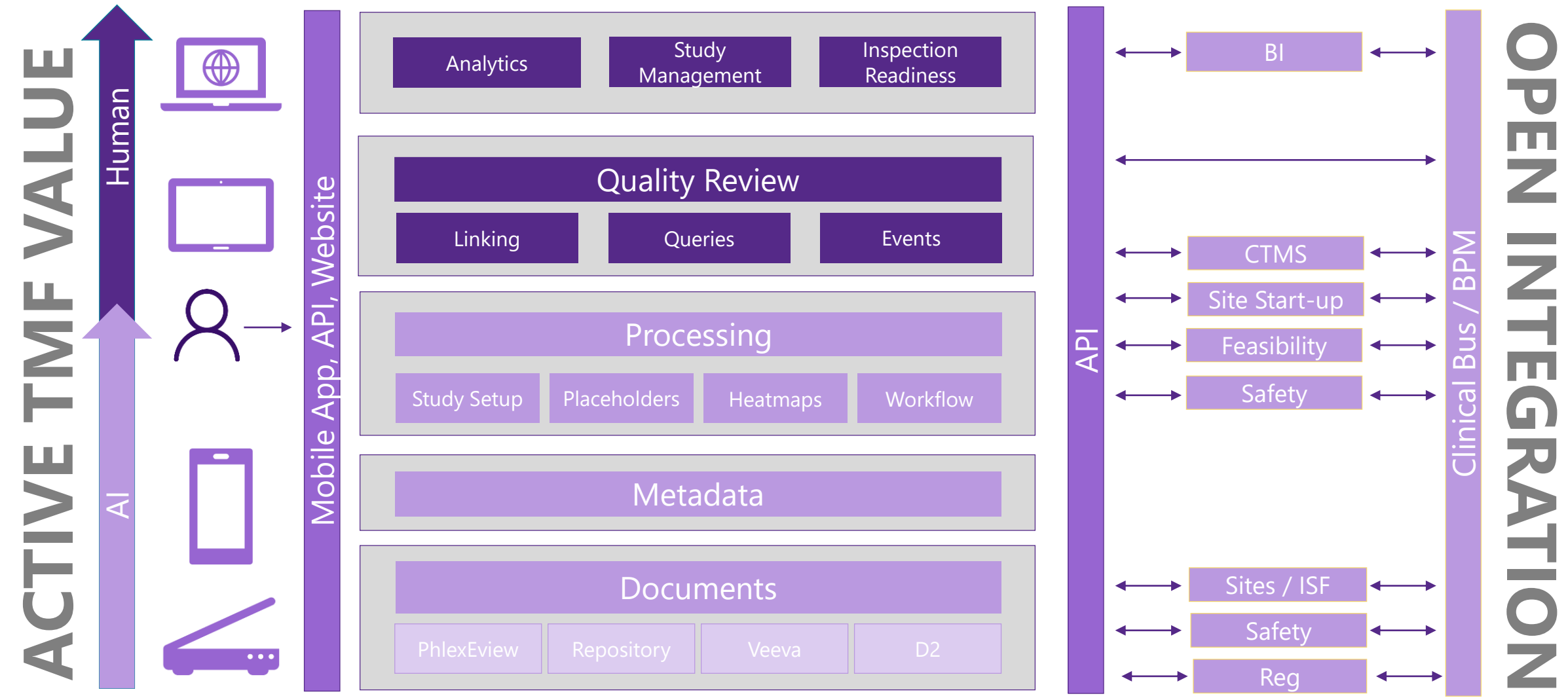
A (near) future vision for eTMF

AI will change the focus of roles supporting and managing the eTMF



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