For MedDRA US User Group

Automation in the Bayer Medical Coding Process

Martina Viell, September 2022

Agenda

- **Bayer Medical Coding is global**
  - Team
  - Coding conventions
  - Clinical trials and pharmacovigilance
  - Integrated systems
- **Coding Process**
  - Autocoding
    - Customised Coding Algorithm
    - Rule-based coding
  - AI/ Machine Learning in Medical Coding
  - Human coding tasks
- **The Business Case for AI**
- **Conclusions**

Bayer Global Medical Coding

One Team

- Coding philosophy, systems and process development driven by Global Medical Coding team, headed by Martina Viell
- Supported by
  - Bayer's Decision Science team
  - Perficient, IT consultancy, long-term collaborative partnership

One set of coding conventions

- Coding against
  - MedDRA
  - MedDRA-J
  - WHO-Drug
  - IDF (Japanese Drug Codes)

Coding across clinical trials and pharmacovigilance

1) Autocoding
2) Artificial Intelligence
3) Human review/ accept
4) Human QA

Multiple integrated systems

- MatchPoint Coder
- Argus
- SAS
- Artificial Intelligence/ Machine Learning

Bayer Global Medical Coding

One Team

One set of coding conventions

Coding across clinical trials and pharmacovigilance

Multiple integrated systems

- Single centralised team with global accountability for coding clinical trials and pharmacovigilance data
- Coding expertise drives
  - Coding strategies
  - Coding philosophies
  - Processes & tools
- Collaboration with related functions
  - Development and maintenance of global coding guidelines for e.g. MedDRA, WHO-Drug
  - Global MedDRA and WHO-Drug Synonym List maintenance and continuous improvement
  - Provision of efficient auto-encoding algorithms
  - Development and maintenance of Medical Term Groupings and Drug Groupings

Bayer Global Medical Coding

One Team

One set of coding conventions

Coding across clinical trials and pharmacovigilance

Multiple integrated systems

- MedDRA/WHO-Drug Coding Conventions
  - Detailed rules for coding with MedDRA/WHO-Drug
  - For MedDRA : Based on the current version of “MedDRA Term Selection: Points to Consider”
- MedDRA/WHO-Drug Synonym Lists
  - Code assignments are based on MedDRA/WHO-Drug Coding Conventions
  - Integrated into the coding tools to
    - Increase the hit rate of the autoencoder
    - Support coding consistency

Bayer Global Medical Coding

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Coding across clinical trials and pharmacovigilance

Multiple integrated systems

- Managing workload/ timelines/ quality of coding of:
  - Internal clinical studies (Phase I to IV)
  - Outsourced studies
  - Non-interventional Studies
  - Cases processed by Global Pharmacovigilance
  - Legacy data re-coding
- Clinical trials data coding:
  - Coded by-text (not by-patient)
  - Unique term basis, identical records are only seen once
- Pharmacovigilance coding:
  - By-patient basis
- Version updates of coding thesauri in accordance with regulatory requirements
  - Review of synonym lists and coding guidelines
  - Refresh of all clinical and drug safety data after MedDRA version updates

Bayer Global Medical Coding

One Team

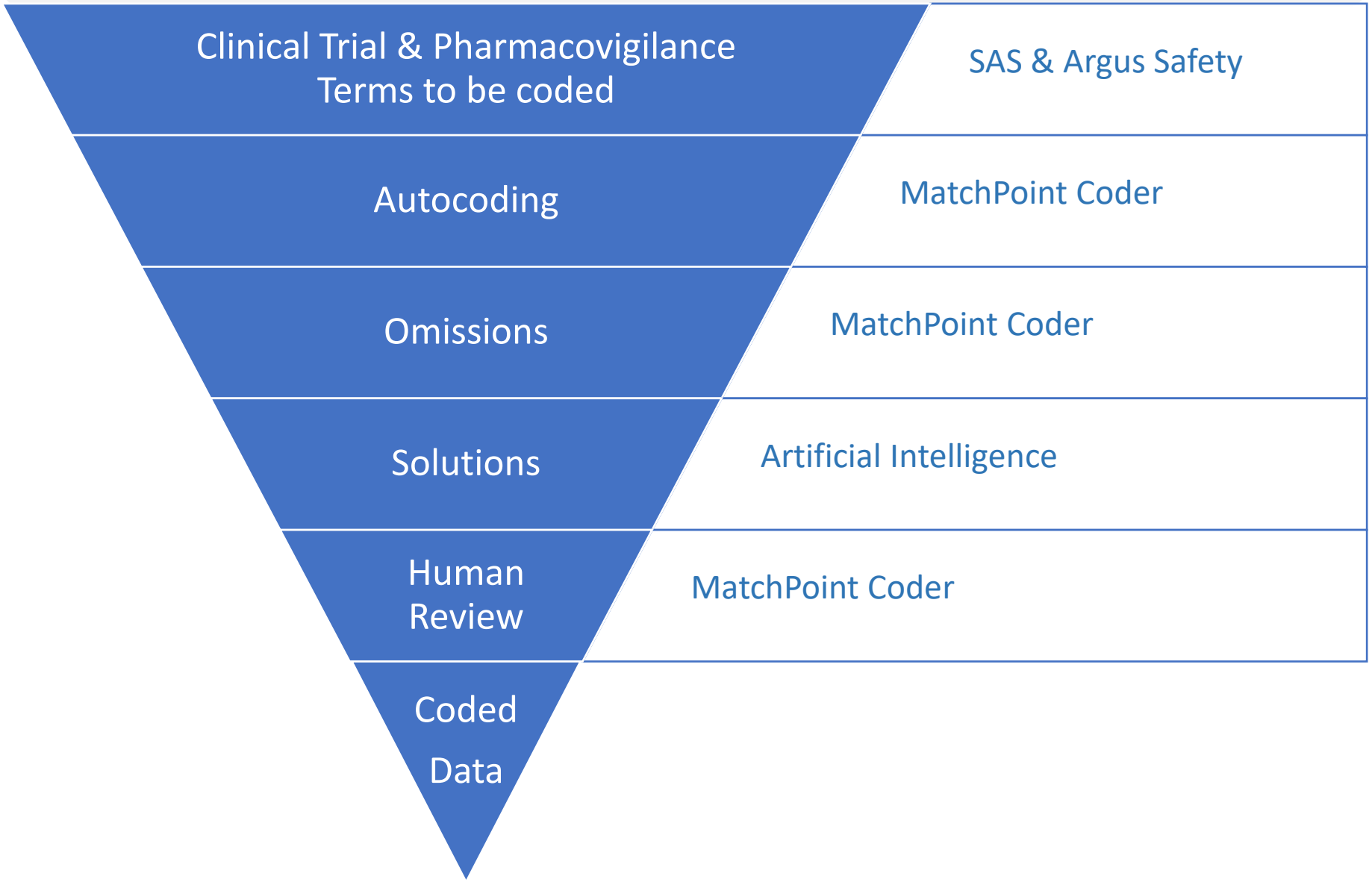
One set of coding conventions

Coding across clinical trials and pharmacovigilance

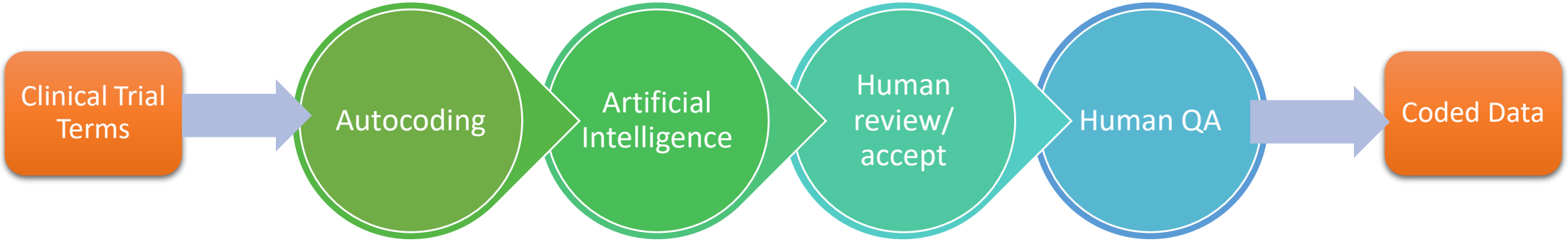
Multiple integrated systems

- MatchPoint Coder
  - Bespoke medical coding system developed in collaboration between Perficient and Bayer
- Argus Safety
- SAS
- Artificial Intelligence/ Machine Learning
  - Watson - IBM Artificial Intelligence
  - Holmes - AI system for MedDRA coding developed within Bayer
  - Koda – AI system for WHO-Drug coding developed by UMC - under consideration for the future

Multiple integrated systems



Four phase coding process triggered within MatchPoint Coder



1) **Autocoding**
   - // 3-stage customised coding algorithm within MatchPoint Coder
   - // Terms are autocoded or an omission is generated
2) **Artificial Intelligence**
   - // Omissions generated by the coding algorithm are passed to AI/ ML to propose a solution
3) **Human review/ accept**
   - // Human accepts or overwrites the proposed solution
4) **Human QA**
   - // Coding is reviewed to ensure adherence to coding conventions and consistency e.g. within a clinical trial

Three stage customised coding algorithm within MatchPoint Coder

1) Exact matches

- In dictionaries
- In company synonym list

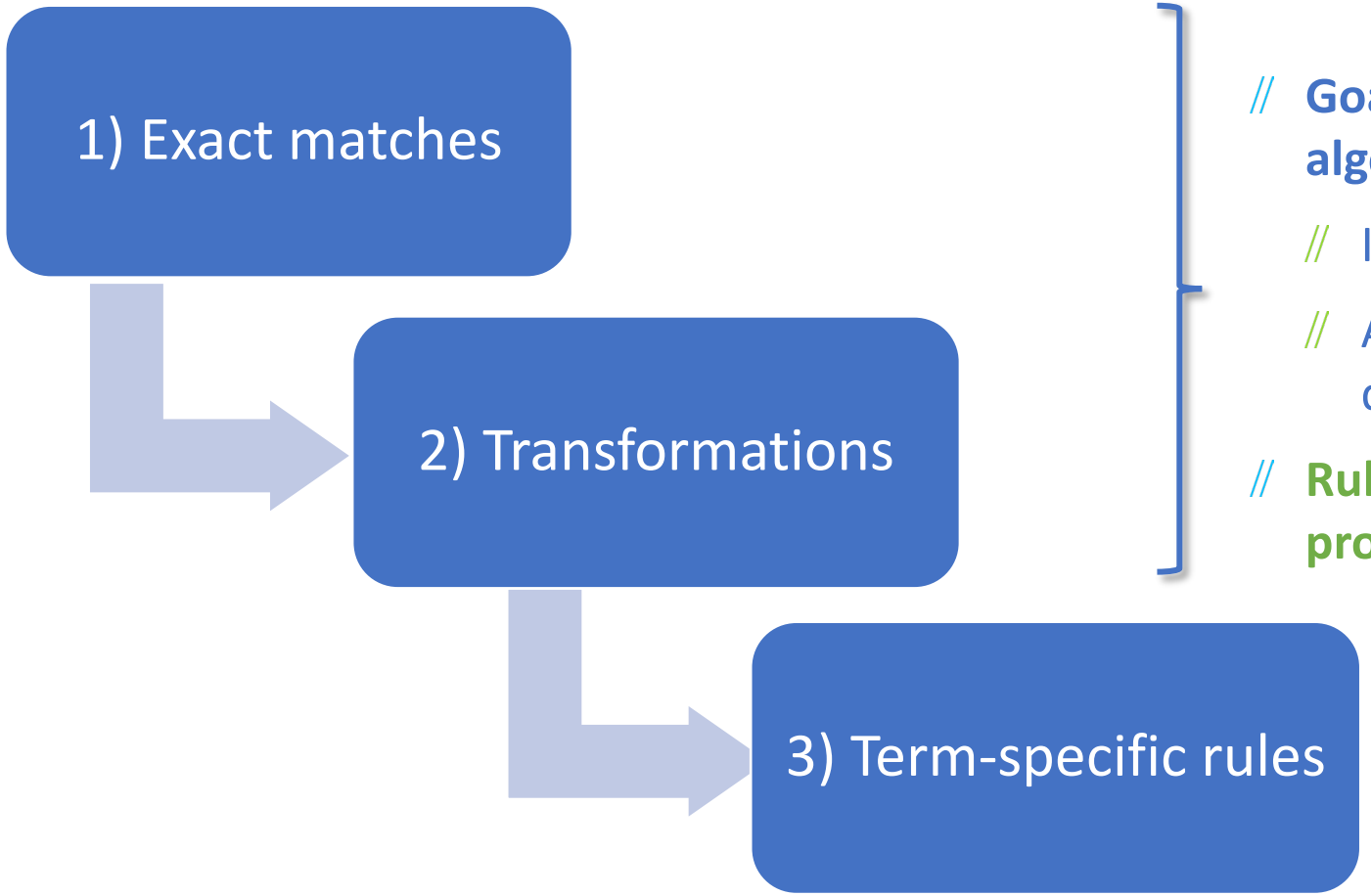
2) Transformations

- Increase likelihood of a match against a dictionary term by passing verbatim through a sequence of transformations (then look-ups against dictionary terms)

3) Term-specific rules

- e.g. specify value ranges for Body Mass Index

Three stage customised coding algorithm within MatchPoint Coder



- **Goals of first two stages of coding algorithm**
  - Increase autocoding hit rate
  - AND have more autoencoded training data available for machine learning (ML)
- **Rule-based coding approach helps ML propose better coding results**

Details that influence coding outcomes

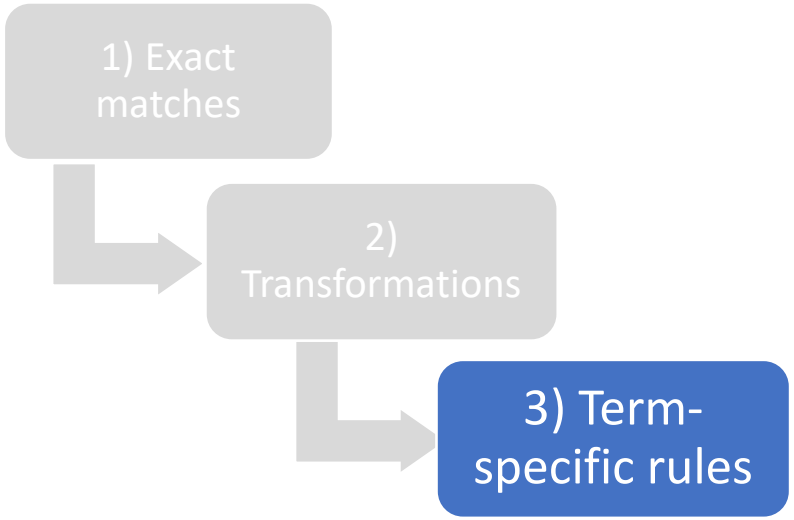
Details that influence coding	Examples
Singular versus plural	• Red spot = Erythema • Red spots = Rash
Left versus right	• Left vs right blindness is irrelevant • Left vs right heart failure is important
Unilateral versus bilateral	• Left oophorectomy • Oophorectomy bilateral • Arm pain, unilateral arm pain, left arm pain, right arm pain: which arm is in pain is not relevant
Qualifiers	• Severe, moderate, mild, important
Verb inflections	• “Hospitalise" verb versus “Hospitalised“, the past tense of the verb • Burning = a sensation • A burn = typically a skin burn

// **Example Transformation within coding algorithm:**

// **Remove *“left”* or *“right”* if related to “*arm*”**

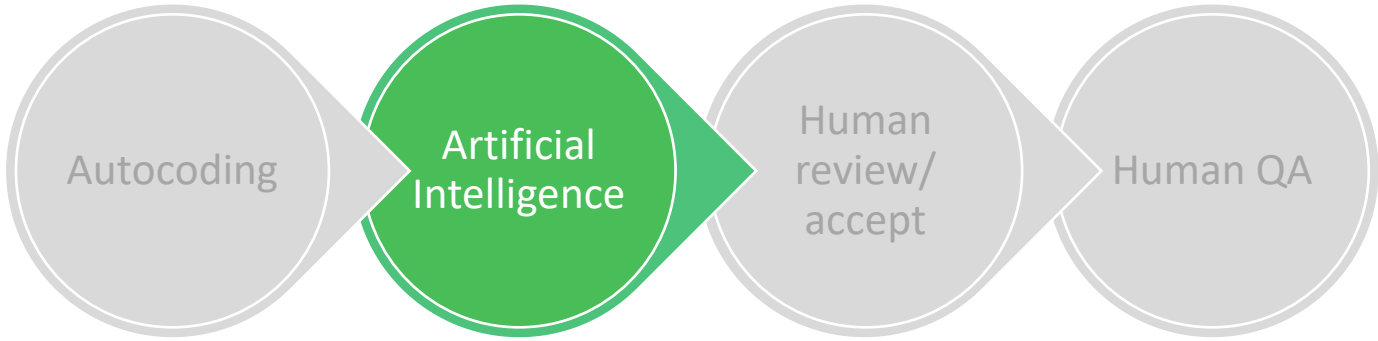
// **Do not remove *“left”* or *“right”* if related to “*heart*”**

Three stage customised coding algorithm within MatchPoint Coder



- Company coding conventions are converted into Term-Specific Rules within the coding algorithm
- Most Term-Specific Rules relate to numbers
  - In general numbers cannot simply be ignored when making coding decisions
  - Numbers can have certain meaning depending on the terms they are associated with e.g. temperature or BMI (more details later)
  - Term-Specific Rule: deals with BMI + value + optional unit

Phase two of coding process involves Artificial Intelligence



- Terms that autocode:
  - Are passed to Artificial Intelligence/ Machine Learning (ML) for training purposes
- Terms that do NOT autocode:
  - Generate omissions and are passed to ML for solutions to be proposed
  - Solutions are reviewed by humans and final decision returned to ML for training

Introduction to Machine Learning and how it can be used in Medical Coding

- **What is Machine Learning**
  - Initial data is used to train a Machine Learning model in order to make predictions on new data, without explicitly being programmed to do so
  - Ongoing training is required to continuously improve the model and therefore quality of predictions
  - Significant volumes of data are required for training
- **How can ML be used in Medical Coding?**
  - ML training data for Medical Coding comprises pairs of terms and codes:
    - Training data = Reported term + corresponding dictionary code
  - Sources of training data:
    - The dictionary (a limited set of pairs of terms and codes)
    - Company synonym list (increases the sets of pairs somewhat)
    - Autoencoded data (increases the sets of pairs even more)

How is Machine Learning used in Medical Coding?

Body Mass Index example

- MedDRA dictionary does not contain ranges of what is over and what is under weight.
  - This depends on company coding guidelines i.e. Term-Specific Rules
  - Bayer/ Perficient belief is that Machine Learning cannot be trained only on MedDRA data, using Natural Language Processing, therefore Term-Specific Rules have been introduced
- Rule-based coding lead to 11,000 pairs of BMI terms with codes to be available for training ML
  - Examples:
    - *"The patient's BMI was 15.123"*
    - *"Patient's BMI was 15.567"*
- Holmes (Bayer's new ML) returns *"underweight"* for these BMI values
  - Via processing volumes of training data Holmes has been trained that
    - "*The patient's*" and "*was*" are superfluous words (removed as part of the transformation stage)
    - However the "*BMI*" text and the number are crucial to the coding, therefore Holmes has learnt that BMI of 15 = underweight (LLT and PT are both *"underweight"*), therefore returns *"underweight"* as the proposed omission solution

How is Machine Learning used in Medical Coding?

Body Temperature example

- Reported term: "*Temperature 40.0 C*"
- MedDRA does not contain: "*Temperature 40.0 C*" (so this does not autocode)
- MedDRA contains: "*Body temperature increased*" and "*Pyrexia*"
  - These are different PTs
- MedDRA does not define the body temperature range for *Pyrexia*
  - Company-specific coding conventions state which temperatures are coded to *Body temperature increased* and which are coded to *Pyrexia*
    - Coding conventions are converted to Term-Specific Rules
    - Term-Specific Rules increase autocoding hit rate
    - Improved autocoding hit rate improves results from Machine Learning

Why invest significant effort in the coding algorithm if you also have Artificial Intelligence/ Machine Learning?

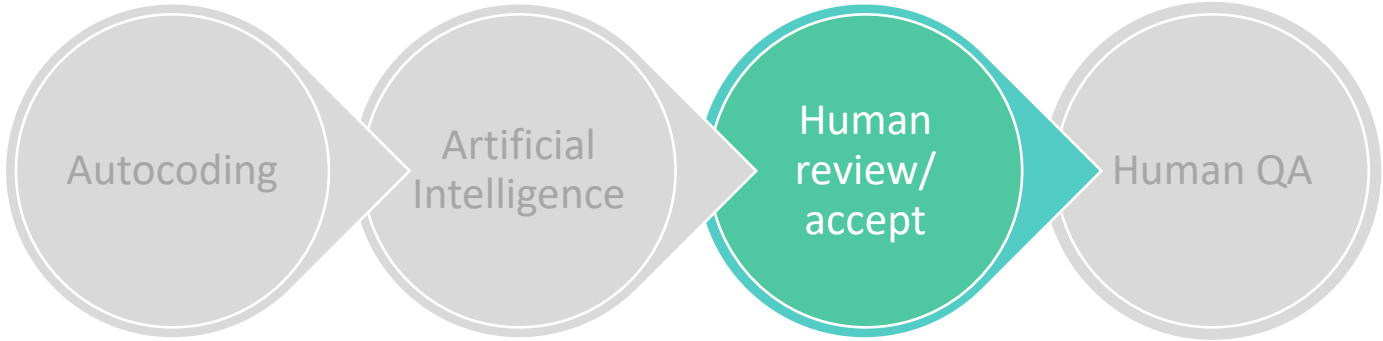
Customised coding algorithm increases autocoding hit rate

- Hits/ autocoded terms require no further processing by ML or human intervention
  - ✓ *Saves time*
- Autocoded terms are supplied to the ML system for training
  - From the MedDRA thesaurus alone it would be difficult for Machine Learning (ML) to determine what text is and is not important within the terms to be coded
  - Training data is essential for Machine Learning to "learn"
    - ✓ *Improves coding results from ML in future*
  - The more terms that autocode the more ML can learn when certain words can be ignored versus when they must not be ignored
    - ✓ *Improves coding results from ML*

Customised coding algorithm produces cleaner data to train the ML even if it cannot autocode the term

- ✓ *Improves coding results from ML*

Third phase of coding process within MatchPoint Coder is Human review/ accept



Human review required after AI/ML

- Machine Learning technology has to be exposed to large volumes of data in order to be trained
- First few times a term is sent to be coded the ML could return unusual results, so human review/ monitoring is required
  - Human feedback trains the system further
- Authorities still expect human involvement in coding decisions

Final phase of coding process Human QA / Coding Review

- Coding (listings) reviewed by Medical Dictionary Experts
- Currently review:
  - 100% of AE
  - Subset of surgeries + Medical History
- Takes place periodically during clinical trials and final Term Review Report at end of trial
- Aim: check for consistency in coding across a clinical trial, or program of trials

The Business Case for AI

- Increasing coding volume
- Higher workload for Medical Coding team
- Skilled employees difficult to hire
- Requires at least one year of training

- Reasons for replacing IBM's Watson with Bayer's Holmes
  - IBM has not communicated any plans to improve the Watson Machine Learning algorithm
  - Technology has changed since Watson for Medical Coding was implemented in 2017
  - For Clinical Trials, at the PT Level
    - 75% of solutions proposed by Watson are accepted
    - 92% of solutions proposed by Holmes are accepted

Outlook

// POC started to use of AI/ ML in coding consistency review e.g. within a clinical trial, or program of trials

Conclusions

- Centralised coding team of experts contribute to development of tools and processes
- Rule-based coding, within customised Coding Algorithm, increases success of Machine Learning
- Human coders still required even after introduction of AI
- There will be further opportunities for using AI in Medical Coding in the future

Thank you!