tcs ADD™

Building on belief

Transparency of artificial intelligence in pharmacovigilance

Introduction

The past decade has witnessed massive technological advancements in the pharmacovigilance (PV) space. The introduction of artificial intelligence (AI), machine learning (ML), robotics, natural language processing (NLP), advanced analytics, voice recognition, and cognitive agents has transformed the traditional pharmacovigilance (PV) paradigm. Cognitive and intelligent platforms have a huge potential to drive safety case processing efficiencies and over time, replace the traditional PV systems. The benefits of automation in PV at scale are clear, and predictions say that nearly 50% of global healthcare organizations will implement artificial intelligence strategies by 2025. The life sciences (LS) industry handles large amounts of health and safety data from research & development, clinical trials, post-marketing, to real-world data. The volume of datasets and metadata has rapidly exceeded the capability for humans to process, handle, and review them. Despite this, LS has been slower than others to adopt and embrace AI based automations.

Since 1956 when John McCarthy coined the term “artificial intelligence” at the Dartmouth Summer Research Project on Artificial Intelligence (DSRPAI), the concept of machines thinking like humans, or even better, became the topic of science and technology developments. Now in 2022, it is difficult to think of any process that doesn’t use AI and ML and yet, many LS organizations have not adopted the technology. There are multiple reasons, factors, and challenges that can be attributed to the slow adoption rate, but in the present article, we will focus our attention on “transparency”, a factor that explains the interpretation and explainability of AI algorithms and determinations. This peculiar “black box nature of AI models” challenge has made AI driven PV systems to be viewed with apprehension by LS organizations and regulatory authorities.

Artificial intelligence is not infallible with machines and humans missing information, taking wrong determinations, and committing errors. Transparency in AI models shall help understand the nature of errors, improve quality, efficiencies, human governance over machines, and facilitate corrective actions.

What is a transparent AI model?

In pharmacovigilance case processing, AI is primarily used for data extraction, synonym identification, case validity, severity assessment, relationship and listedness, data population through business rules, and duplicate checks.

In a highly regulated area like safety, transparency becomes critical to:

i. Understand the AI-based decision rationale

ii. Track and have access to all decisions at any time

To respond to the above key points, we will first define “transparency or explainability”. Explainable AI refers to a set of techniques that demonstrates how an AI-ML algorithm arrives at a set of outputs (predictions). It allows humans to access, understand, trust, and perform actions over the output(s) from complex, and in most cases, “black box” models (Fig.1). Transparency helps decision makers know the relevant decision tree determinations and data characteristics driving the output.

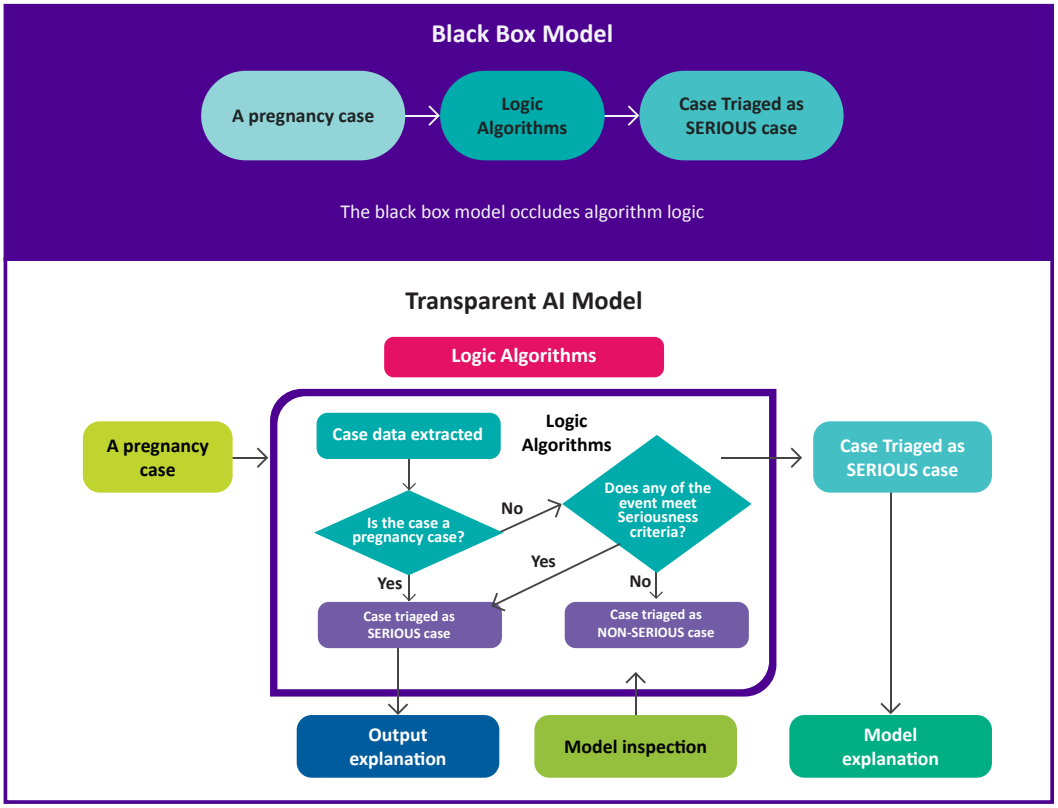
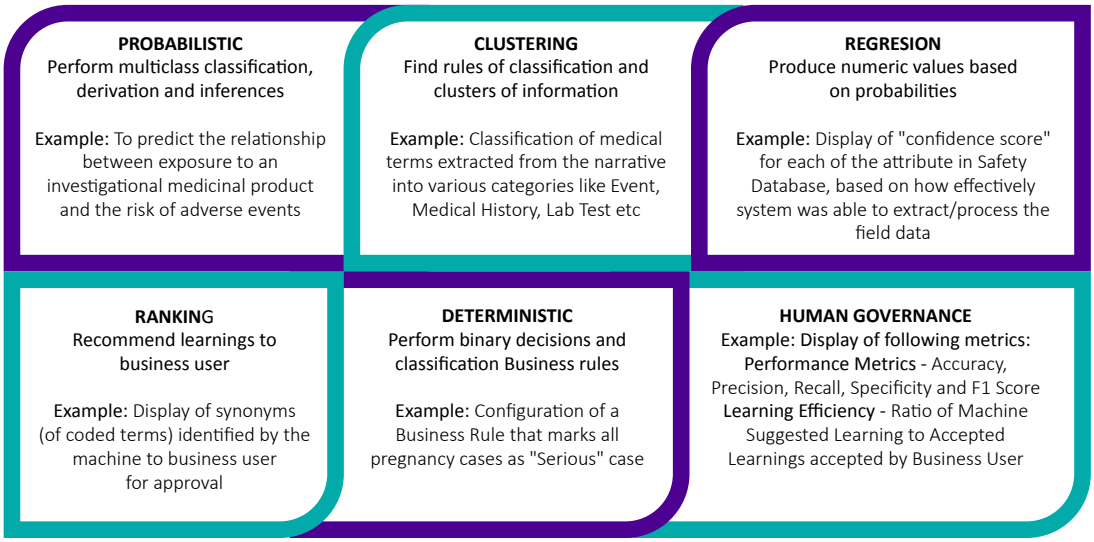


Figure 1: Black box vs transparent AI model

Characteristics of a transparent AI model

In a highly regulated environment like PV, transparency becomes essential. The following visual illustrates and enunciates the basic characteristics of the AI transparent model to fulfil regulatory and industry requirements:



1. Transparent AI-ML in data extraction:

The following example illustrates the extraction of Safety Case Attribute using various deterministic and probabilistic techniques. Some of the techniques used include Regular Expressions, Dictionary, or synonym matching, Ruled-based Named Entity Recognition (NER).

The below table displays the specific string and the relationship between the words that enabled the algorithms to perform data extraction.

Input: The source document with the following text: A 54-year-old man was suffering from throat ulcer since 01-Jan-22 and was admitted into the hospital two days later.

Output: The extracted attributes, attribute values, and details related to extraction are displayed below:

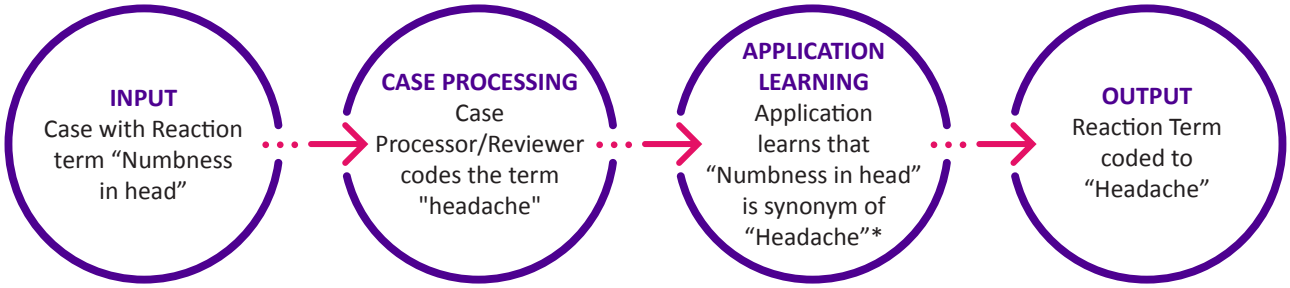
Safety Case Attribute	Value of the attribute	Word(s) of interest	String from which attribute extracted	Relationship between the words
Hospitalization	Yes	Hospital	admitted into the hospital	<Admitted> in conjunction with <hospital>
Date of Hospitalization	3-Jan-22	1-Jan-22	01-Jan-22 and was admitted into the hospital two days later	<two days later> in conjunction with <01-Jan-22>
Patient Age	54	54 years	The 54-year-old man	<54> in conjunction with <Years>
(in years)	54	54 years	The 54-year-old man	<54> in conjunction with <Years>
Patient Sex	Male	Man	54-year-old man	<man> in conjunction with <suffering> and<throat ulcer>

2. Transparent AI in automated coding:

Synonym Dictionary is a critical component for accurate extraction of Safety Case Attributes. The enrichment of Synonym Dictionary can happen either manually or through Machine Learning Algorithms. The below examples cover:

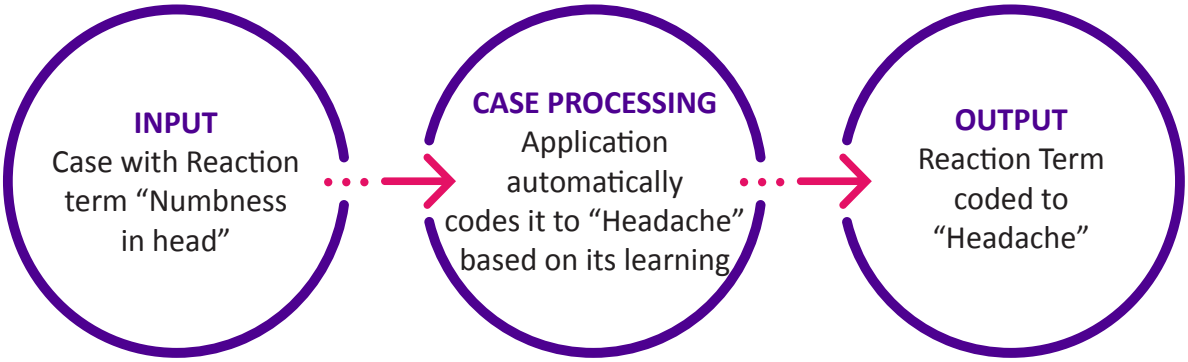
- Application learns a new synonym of reaction term through Machine Learning
- Application performs automated Coding based on approved synonym
- Transparent AI in auto-coding through synonym

Application learns the synonym of reaction term through Machine Learning



*Machine learnings need to be approved by human business user as part of human governance.

Application auto codes the verbatim to MedDRA term based on its approved learning



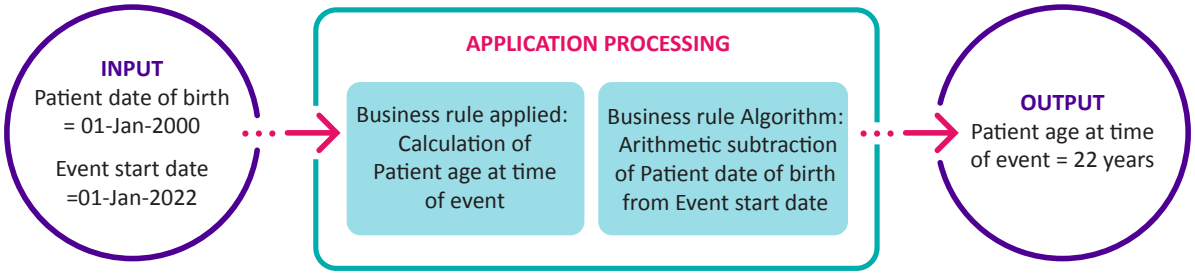
Transparent AI in auto-coding through synonym

Safety Case Attribute	MedDRA Decode	Synonym	Source of the synonym
Reaction term	Headache	Numbness in head	Identified during Re-inforced learning **
**Reinforced learning – This learning takes place from reconciliation of the information from case processed by a machine with the same case amended or changed by the humans			

3. Transparent AI in safety case attribute population through business rules

Business Rules define the conditions under which Safety Case Attributes can be inferred based on available information.

Business Rules utilize Deterministic algorithms to make inferences.



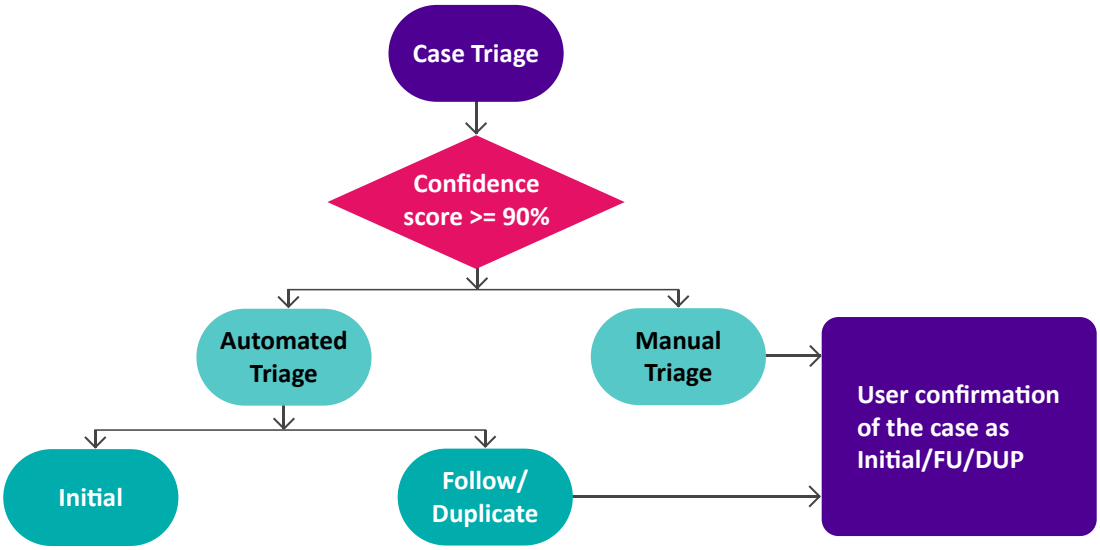
Transparency is brought in the rule-based AI system by displaying the business rule and its description which were triggered for population of a particular case attribute.

Safety Case Attribute	Data populated	Business rule applied	Description of rule
Patient age at time of event	22 years	Calculation of patient age at time of event	Calculated by date of birth subtracted from event start date

4. AI-based determination of incoming case as Duplicate, Follow-up, New

A case in the AI-enabled application is determined to be Duplicate, Follow-up, New based on a "confidence score". This score is calculated based on predefined algorithms.

The confidence score above a certain threshold determines that the case triage can be done through automation.



AI transparency is achieved by displaying the confidence score and the algorithms used for its calculation.

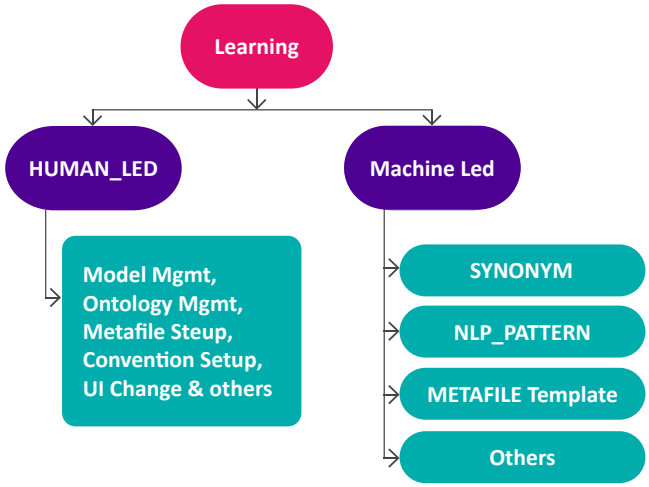
Based on the displayed information, the human user can make informed decisions and continuously recommend changes to the confidence score algorithms.

Learning through Human Governance

There are two types of learning that a cognitive AI-driven PV system can have:

i. Human-led learning

ii. Machine-led learning



Machine-led learning can have wrong learnings and wrong determinations; that is why it is essential to introduce human governance and supervision in the application to ensure inter-reliance between humans and machines.

The user should always be able to review and approve or reject any learning generated by the machine. This is also essential when considering the regulatory sensitivity of the PV domain. In addition, the system should enable complete traceability of actions with logs for new pattern identification to keep the quality high and compliant even as data evolves and changes.

Conclusion

Transparency in the AI-driven pharmacovigilance system is directly linked to the improvement of AI capabilities and reduction of errors. It provides an opportunity to identity gaps in the models and update the algorithms and business rules accordingly. An AI model based on transparent algorithms where decisions are visible, feels trustworthy in the life sciences industry and for regulatory bodies. Based on the 2021 guidelines from The International Coalition of Medicines Regulatory Authorities (ICMRA), sponsors, developers and pharmaceutical companies should establish strengthened governance structures to oversee algorithms and AI deployments that are closely linked to the benefit/risk of a medicinal product. We believe that AI transparent models capable of emerging with the current industry guidelines are critical in driving the adoption of AI technologies in pharmacovigilance.

About the Authors

Tejas Almelkar

Tejas Almelkar currently works as a Product Manager for TCS ADD™ Safety. He comes with extensive experience in pharmacovigilance, banking, and healthcare domains. In his current role, Tejas is working on leveraging artificial intelligence and machine learning to create applications that could benefit the society.

Alejandra Guerchicoff, Ph.D.

Dr. Alejandra Guerchicoff is a Ph.D. in Molecular Genetics with a post-doctoral training in molecular cardiology. She is working as an Industry Advisor for TCS ADD™ Safety. Dr. Guerchicoff possesses a rich experience of more than 20 years in clinical research, and post-marketing pharmacovigilance for medical devices, drugs, combination products, gene and cell therapy, and software-as-medical-device products. She has authored many prestigious journal publications and books on diverse subjects and different therapeutic areas. In her current role, Dr. Alejandra Guerchicoff is working for the development of pharmacovigilance innovative technology solutions with the use of artificial intelligence and other modern technologies across various life sciences operations.

TATA CONSULTANCY SERVICES

Awards and accolades

#1 IN CUSTOMER SATISFACTION 2020/21 EUROPE Whitelane Research

top EMPLOYER NORTH AMERICA 2021 CERTIFIED EXCELLENCE IN EMPLOYEE CONDITIONS

top EMPLOYER GLOBAL 2020 CERTIFIED EXCELLENCE IN EMPLOYEE CONDITIONS

ASIA'S OUTSTANDING COMPANIES POLL 2020 ASIAMONEY

STEVIE AWARD 2020

CONGRATULATION CIO 100 WINNERS 2020

FinanceAsia ASIA'S BEST COMPANIES 2020

DIGITAL IMPACT AWARDS WINNER

CANADIAN HR AWARDS 2020

50 POINTS OF LIGHT

FTSE4Good

CDP DISCLOSURE INSIGHT ACTION

2020 Brand Finance® Awards

TOP 3 IT SERVICES BRAND

2020 Brand Finance® Awards

FASTEST GROWING IT SERVICES BRAND FOR THE DECADE 2010 - 2020

AWARDED Superbrands BRITAIN'S CHOICE 2020

AWARDED Superbrands AMERICA'S CHOICE 2020

About TCS ADD™ Platforms

TCS ADD™ is a modern and open drug development platform for life sciences that enables digital ecosystems, simplifies data complexity and provides faster access to new and effective drugs for patients in need. The platform is powered by our proprietary cognitive intelligence engine data driven smart analytics and Internet of Things (IoT) that makes clinical trials more agile and safe. TCS ADD™ leverages the best of cloud architecture and personalized user experience design in compliance with quality guidelines and privacy regulations.

To know more

Visit the https://www.tcs.com/tcs-add page on www.tcs.com

Email: add.platform@tcs.com

About Tata Consultancy Services Ltd (TCS)

Tata Consultancy Services is a purpose-led transformation partner to many of the world's largest businesses. For more than 50 years, it has been collaborating with clients and communities to build a greater future through innovation and collective knowledge. TCS offers an integrated portfolio of cognitive powered business, technology, and engineering services and solutions. The company's 500,000 consultants in 46 countries help empower individuals, enterprises, and societies to build on belief.

Visit **www.tcs.com** and follow TCS news **@TCS**.

Corporate Marketing | Design Services | M | 11 | 22