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Reference: EMA Reflection Paper on the Use of Artificial Intelligence (AI) in the Medicinal Product Lifecycle-draft Reference No. EMA/CHMP/CVMP/83833/2023

Over the last few years, the potential application of Artificial Intelligence has greatly expanded. As this rapidly evolving field continues to advance, questions regarding the application of AI in the pharmaceutical industry have arisen. In response to this, the European Medicines Agency (EMA) distributed the draft *Reflection Paper, The Use of Artificial Intelligence (AI) in the Medicinal Product Lifecyle* for public comment from July 19, 2023 to December 31, 2023.

A team of PDA members that are experts in the topic area were convened to provide a response to the comment solicitation in this quickly evolving subject of great importance to the industry.

PDA is a non-profit international professional association of more than 10,000 individual members scientists having an interest in fields of pharmaceutical, biological, device manufacturing, and quality. Our comments have been prepared by a committee of PDA members with expertise in the areas covered in the Reflection Paper on behalf of PDA's Scientific Advisory Board.

PDA (Parenteral Drug Association®) Response to EMA's Reflection Paper on the Use of Artificial Intelligence (AI) in the Medicinal Product Lifecycle (Draft Paper)

A. General comments on the draft reflection paper

General Comments	Is this a MAJOR concern/comment? [Yes; No]
Comment: PDA acknowledges that the reflection paper makes reference to emerging use cases for AI/ML across the medicinal product development lifecycle, however, the primary focus and examples are in pre-clinical and clinical phases. **Proposal:** PDA proposes expanding guidance to specify activities and use cases implied in reference to authorization and post authorization phases, (e.g., commercial manufacturing and process adjustments, quality management and deviation trending, etc.).	Yes
Comment: The AI act (Reference 3) cites products falling under the EU's Product Safety Legislation as falling into the category of "high-risk" which specifically includes medical devices but does not include medicinal products. **Proposal:** PDA suggests providing an interpretation and/or correlation to the AI act (e.g., does "High-Risk" in section 2.2.4 Precision Medicine refer to the "High Risk" category in the AI act?).	Yes
Comment: In reference to lines 285-286, how will a satisfactory and an unsatisfactory test performance be defined? What reference parameter will be used to identify this? **Proposal:** PDA proposes a reference parameter be included to identify unsatisfactory test performance.	Yes
Comment: The document places the use of AI/ML under the spotlight but is not clear on exactly what will be expected or how a company can meet those expectations. **Proposal:**	Yes

PDA suggests providing more details in terms of the expectations the Regulatory Body has. Is there a plan for publication of outcomes of the EMA QIG engagement to produce recommendations for human and veterinary medicines? (e.g., revision of this paper? another/new document formation?)	
Comment: The paper sets out strict criteria for model documentation but does not provide guidance regarding the use of proprietary algorithms and third parties. **Proposal:** PDA suggests including such guidance.	Yes
Comment: It would be helpful to the reader to include an "out of scope" section and to exclude "traditional" software programs, in particular process control, where systems perform automatic adjustments based on setpoints, etc..	No
Comment: The term "Artificial Intelligence (AI)" can be too broadly interpreted. Use of the term "advanced algorithms" may be more appropriate given the role this technology plays in the pharmaceutical manufacturing industry.	Yes
Comment: Given the broad scope of this reflection paper and the expanded terminology around this topic, PDA recommends the addition of the following terms to the glossary to aid the reader and promote clarity: advanced algorithms, AI-based dynamic systems, AI-based static systems, Black Box (model/system), foundational models, freezing of dynamic AI models, Generative Artificial Intelligence (GenAI), learning, poor data quality, rule-based static systems, synthetic data, and training.	Yes

B. Specific comments on the draft reflection paper by section

Section 1: Introduction *(lines 44-82)*

Line number(s) of the relevant text (e.g., 20-23)	Comment	Rationale for change	Proposed change	Is this a MAJOR concern/ comment? [Yes; No]

46-49	PDA proposes to substitute "intelligent behaviour" with "rule-based behaviour" Additionally, PDA suggests the additional text to follow the sentence to reflect the current, more realistic situation. **Current Text:** "The utilisation of artificial intelligence (AI) – systems displaying intelligent behaviour by analysing data…that enables increased use of data for analysis and decision-making."	AI systems do not provide intelligent behaviour. ML algorithms provide rule-based behaviour.	**Proposed Change**: "The utilisation of AI – systems displaying **rule-based behaviour** by analysing data and taking actions with some degree of autonomy to achieve specific goals – is an important part of the digital transformation that enables increased use of data for analysis and decision-making. **As described in ICH Q9, applying a risk analysis to model decision making so that a rationale can allow the model to derive a decision and next steps (for low-to no-risk to-patient activities), and human decision making based on the results of the model must be applied to moderate and high risk to patient activities."**	Yes
49-51	The current text is inaccurate. PDA suggests removing "...without explicit programming" and adding the suggested text to clarify algorithms are trained to generate models. **Current Text:** "Such systems are often developed through the process of Machine Learning (ML) where models are trained from data without explicit programming."	Algorithms are trained with data while models are the result of the data and algorithm. The training is supported by a specific program including the algorithm and data can be specifically selected for an intended use.	**Proposed Change**: "Such systems are often developed through the process of machine learning (ML) **where algorithms developed for a general or specific purpose are trained with data to generate models."**	Yes
51-54	PDA proposes replacing "technologies" with "models" and to include wording that also considers GMPs and not only clinical studies regarding introduced risks. **Current Text:**	GMPs should also be considered.	**Proposed Change**: "However, as these **models** often use exceptionally great numbers or trainable parameters arranged in non-transparent model architectures, new risks are introduced that need to be mitigated to ensure the safety of	Yes

	"However, as these technologies often use exceptionally great numbers of trainable parameters...to ensure the safety of patients and integrity of clinical study results."		patients and integrity of clinical study results **as well as GMP-impact decisions."**	
54-55	PDA recommends adding "or based on deterministic equations" after "data-driven", substituting "AI/ML applications with "ML models" and including other potential issues apart from "bias". Additionally, PDA suggests considering ethics as well as trustworthiness of AI. **Current Text:** "Also, as the overarching approach is inherently data-driven, active measures must be taken to avoid the integration of bias into AI/ML applications and promote AI trustworthiness."	The industry is actively using metabolic/mechanistic models or even hybrid models. AI is not the same as ML (AI is umbrella term). While "bias" might be an umbrella term, it is strongly associated with data selection and labeling.	**Proposed Change**: "Also, as the overarching approach is inherently data-driven **or based on deterministic equations**, active measures must be taken to avoid the integration of bias **and other errors (via data or model architecture). Also to be avoided are assumptions or excessive weight being given to certain types of inputs that could impact the accuracy of output** into **ML models** and **detract from** AI trustworthiness **and ethical standing**."	Yes
57-60	PDA suggests adding "manufacturing" after "development". **Current Text:** "…when these emerging technologies are applied to support safe and effective development and use of medicines."	Manufacturing should be included in the product lifecycle considerations.	**Proposed Change**: "Given the rapid development in this field, the aim of this reflection paper is to reflect on the scientific principles that are relevant for regulatory evaluation when these emerging technologies are applied to support safe and effective development **manufacturing** and use of medicines."	No
61-63	Regulators would most likely review more than data. **Current Text:**	The proposed change in text would provide clarification on	**Proposed Change**: "It is crucial to identify aspects of AI/ML that would fall within the remit of EMA or the National Competent Authorities of the Member	Yes

	"…as the level of scrutiny into data assessment will depend on this remit."	what the regulators would focus on and what is meant by "assessment" in this sentence (e.g., is it drug approval only or also inspections, etc.?).	States as the level of scrutiny into data **and model development and maintenance** during assessment will depend on this remit."	

Section 2 Discussion

Section 2.1 General considerations *(lines 84-113)*

Line number(s) of the relevant text (e.g., 20-23)	Comment	Rationale for change	Proposed change	Is this a MAJOR concern/ comment? [Yes; No]
90-92	A Digital Management System is not mentioned anywhere in the document. PDA suggests adding additional text for managing digital assets. **Current Text:** "…performance monitoring of AI and ML tools allow developers to pro-actively defining the risks to be managed throughout the AI and ML tool lifecycle."	Proper rationale from a risk-based approach for use of ML is the foundation to its proper use.	**Proposed Change**: "A risk-based approach for development, deployment and performance monitoring of AI and ML tools allows developers to pro-actively **define** the risks to be managed throughout the AI and ML tool lifecycle. Existing systems (e.g., QRM, QMS, etc.) should be utilized and applied to each model decision and for digital asset management throughout the lifecycle."	Yes
92	PDA suggests adding "and patient" after "regulatory". **Current Text:**	Impact on the patient should be the primary focus.	**Proposed Change**: "The concept of risk includes, but is not limited to, regulatory **and patient** impact."	No

	"The concept of risk includes, but is not limited to, regulatory impact."			
93-95	There could be other causes of negative impact apart from system malfunction and degradation. E.g., poor understanding of the business process that the model is being applied to, poor design, or lack of understanding of the model itself. This underscores the importance of active QRM from as early as possible. PDA recommends removing "system malfunction or degradation of model performance" with "undetected model flaw or drift in its output" to reflect other causes. **Current Text:** "Advice on risk management will be further reflected in future regulatory guidance, as the impact of system malfunction or degradation of model performance can range from minimal to critical or even life-threatening."	"System malfunction" implies that the model stops working as expected.	**Proposed Change**: "Advice on risk management will be further reflected in future regulatory guidance, as the impact of **undetected model flaw or drift in its output** can range from minimal to critical or even life-threatening."	Yes
96-97	There are tools to measure AI model degradation allowing to detect potential malfunctions in advance. AI Model drifting and data drifting are examples of factors that need to be monitored, providing a valuable indicator for decision making in regards of model degradation. Risk management in the	Risk management applied to AI cannot be considered under the same perspective as classical systems. The inherent	**Proposed Change**: "In addition, the degree of risk may vary throughout the lifecycle of the AI-system. **Systems for monitoring data and models may vary throughout the lifecycle**."	No

	context of AI must be automatized with tools that bring a permanent assessment. PDA suggests adding "including data and model monitoring systems" after "AI-system." **Current Text:** "In addition, the degree of risk may vary throughout the lifecycle of the AI-system."	technological dimension of AI requires a specific approach.		
108-109	PDA proposes adding clarity regarding standards by removing the text. **Current Text:** "Of note, these requirements may in some respects be stricter than what is considered standard practice in the field of data science."	The current text is not clear in what ways it would be stricter, as it is subjective.	**Proposed Change:** **Remove the sentence**, "Of note, these requirements may in some respects be stricter than what is considered standard practice in the field of data science."	Yes
110-113	PDA recommends adding "training and validation" before "data" and adding "including accuracy of the model's output" at the end of the sentence to clarify standards to be met to avoid confusion with full DI principles. **Current Text:** "For all requests…the integrity of data and generalizability of models to the target population and for a specific context of use."	Clarification is needed on the meaning of "integrity of data". It would be helpful to understand what standard of "integrity" needs to be met. ALCOA+ is not currently achievable and needs to be adapted/tailored.	**Proposed Change**: "For all requests for advice or opinions the applicant or MAH is expected to provide a scientific base along with sufficient technical details to allow comprehensive assessment of any AI/ML systems used in the medicinal product lifecycle, the integrity of **training and validation** data and generali**s**ability of models to the target population and for a specific context of use, **including accuracy of the model's output**."	Yes

		For example, having the output labeled with % confidence might be equivalent to "Accurate" but this may not be achievable for more complex models.		

2.2 AI in the lifecycle of medicines *(lines 114-116)*

Line number(s) of the relevant text (e.g., 20-23)	Comment	Rationale for change	Proposed change	Is this a MAJOR concern/ comment? [Yes; No]
118-119	PDA proposes substituting "AI" with "advanced algorithms". **Current Text:** "The application of AI in the process of drug discovery…"	Clarity: There is a mixture of terms throughout the document. Only AI is mentioned in the current text.	**Proposed Change**: "The application of **advanced algorithms** in the process of drug discovery may be a low risk setting from a regulatory perspective, as the risk on non-optimal performance often mainly affects the sponsor."	Yes

2.2.1 Drug discovery *(lines 117-124)*

Line number(s) of the relevant	Comment	Rationale for change	Proposed change	Is this a MAJOR concern/ comment? [Yes; No]

text (e.g., 20-23)				
121-124	PDA suggests adding "poor quality" after "mitigate". **Current Text:** "In this context, all models and datasets used would normally be reviewed by the sponsor to mitigate ethical issues…"	AI models rely heavily on data for training, and if the data used is of poor quality or biased, it can lead to inaccurate predictions and decisions.	**Proposed Change**: "In this context, all models and datasets used would normally be reviewed by the sponsor to mitigate **poor quality,** ethical issues, risks of bias and other sources of discrimination of non-majority genotypes and phenotypes from a data quality and quantity perspective (see Technical aspects – Data acquisition and augmentation)."	Yes

2.2.2 Non-clinical development *(lines 125-134)*

Line number(s) of the relevant text (e.g., 20-23)	Comment	Rationale for change	Proposed change	Is this a MAJOR concern/ comment? [Yes; No]
132-134	PDA suggests replacing "data mining" with "machine learning". **Current Text:** "…a medicinal product should be analysed in accordance with a pre-specified analysis plan, prior to any data mining."	The term "data mining" has not yet been used or defined in the document as opposed to "machine learning".	**Proposed Change**: "Any preclinical data that that is potentially relevant for assessment of the benefit-risk balance of a medicinal product should be analysed in accordance with a pre-specified analysis plan, prior to any **machine learning."**	No

2.2.3 Clinical trials and 2.2.3.1 Good clinical practice (GCP) *(lines 135-146)*

Line number(s) of the relevant	Comment	Rationale for change	Proposed change	Is this a MAJOR concern/ comment? [Yes; No]

text (e.g., 20-23)				
139-142	PDA suggests adding the abbreviation "CTA" after "clinical trial application" for consistency. **Current Text:** "…at the time of market authorisation or clinical trial application."	CTA is already included in the glossary.	**Proposed Change**: "Of note, if a model is generated for clinical trial purposes, the full model architecture, logs from modelling, validation and testing, training data and description of the data processing pipeline would likely be considered parts of the clinical trial data or trial protocol dossier and thus should be made available for comprehensive assessment at the time of market authorisation or clinical trial application **(CTA)."**	No

2.2.3.3 Data analysis and inference *(lines 161-187)*

Line number(s) of the relevant text (e.g., 20-23)	Comment	Rationale for change	Proposed change	Is this a MAJOR concern/ comment? [Yes; No]
162-165	PDA suggests changing "AI/ML models" to "data processing scripts" because AI models are not intended to transform data. **Current Text:** "When AI/ML models are used for transformation or analysis of data…"	Specialized scripts and libraries are specifically designed for transforming data. Usually, data transformation is managed by scripts (e.g., data clean-up algorithms performed in python or R) to clean data and generate meta-data. Therefore, these scripts should	**Proposed Change**: "When **data processing scripts** are used for **data** transformation or analysis of data within a clinical trial of a medicinal product, they are considered a part of the statistical analysis and should follow applicable guidelines on statistical principles for clinical trials (see Section 5) and include analysis of the impact on downstream statistical inference."	Yes

		be part of the elements to be controlled and they should be managed as software in regulated environments.		
185	PDA recommends adding verbiage after the sentence to address selected and developed algorithms. **Current Text:** "Once a dataset has been opened, any non-prespecified modifications to data processing or models implies that analysis results are considered *post hoc* and hence not suited for confirmatory evidence generation."	Data pre-processing is considered a part of the AI lifecycle, but AI algorithm governance is never considered.	**Proposed Addition**: Add after sentence, "**Selected and developed algorithms, including the scripts and libraries used in the AI model process, must be properly documented and managed."**	Yes
186-187	PDA suggests adding "to ensure visibility and clarity of the models" after "open repository". **Current Text:** "…models are published in an open repository prior to their deployment…"	Clarity is needed regarding the request for an "open repository".	**Proposed Change**: "If possible, it is encouraged that models are published in an open repository **to ensure visibility and clarity of the models** prior to their deployment in a pivotal clinical trial."	Yes

2.3 Regulatory interactions *(lines 233-253)*

Line number(s) of the relevant	**Comment**	**Rationale for change**	**Proposed change**	**Is this a MAJOR concern/ comment? [Yes; No]**

text (e.g., 20-23)				
244-245	PDA suggests removing "based" from the term "AI based models" for clarity. **Current Text:** "Timing of interactions should be guided by the regulatory impact and risk associated with using the AI based models in context of the lifecycle of a medicinal product."	An AI based model is the same as an AI model.	**Proposed Change**: "Timing of interactions should be guided by the regulatory impact and risk associated with using the **AI models** in context of the lifecycle of a medicinal product."	Yes

2.4 Technical aspects and 2.4.1 Data acquisition and augmentation *(lines 254-280)*

Line number(s) of the relevant text (e.g., 20-23)	Comment	Rationale for change	Proposed change	Is this a MAJOR concern/ comment? [Yes; No]
260-262	PDA suggests replacing "potential biases" with "poor data quality" for a well-rounded consideration. **Current Text:** "Dedicated reflections will be necessary to identify potential biases applicable to…"	Bias is only one of the possible data issues that must be considered before creating AI models. There are multiple good practices in data science to determine defects in data representation, including bias, e.g., un-represented samples, anomalies, outliers,	**Proposed Change**: "Dedicated reflections will be necessary to identify **poor data quality** applicable to veterinary medicines considering the differences e.g., in target populations and regulatory requirements between veterinary and human medicines."	Yes

		etc. These tools should be considered as part of the bias analysis.		
263-265	PDA proposes adding verbiage after the sentence for clarity. **Current Text:** "…should be documented in a detailed and fully traceable manner in line with GxP requirements."	Addition provides clarity of GxP regarding a QA approved rationale.	**Proposed Addition**: Add after sentence, **"A Quality approved rationale should support these decisions."**	No

2.4.2 Training, validation, and test data *(lines 281-296)*

Line number(s) of the relevant text (e.g., 20-23)	Comment	Rationale for change	Proposed change	Is this a MAJOR concern/ comment? [Yes; No]
282-283	PDA suggests keeping "validation for intended use" as the overarching term, including data validation and model performance verification. Add the proposed verbiage after the sentence. **Current Text:** "It should be noted that the term validation is used differently in the field of AI/ML and medicines development."	To be consistent with current CSV/CSA terminology.	**Proposed Addition**: Add after sentence, **"However, all models are to be appropriately tested (i.e., confirmed, qualified, or validated) for their intended use."**	Yes
286-288	PDA recommends removing the sentence.	Updating a model without testing versus the original	**Proposed Change**: **Remove sentence**, "If test performance is unsatisfactory and further development is	Yes

	Current Text: "If test performance is unsatisfactory and further development is needed, the current test data set *de facto* becomes a second-stage validation set and a completely new and independent test dataset is needed to repeat the test procedure for an updated model."	validation dataset does not prove that the model has improved.	needed, the current test data set *de facto* becomes a second-stage validation set and a completely new and independent test dataset is needed to repeat the test procedure for an updated model."	

2.4.3 Model development *(lines 297-315)*

Line number(s) of the relevant text (e.g., 20-23)	Comment	Rationale for change	Proposed change	Is this a MAJOR concern/ comment? [Yes; No]
298-299	General system development lifecycle principles still apply. PDA proposes adding the suggested verbiage after the sentence. **Current Text:** "Given the plethora of modelling approaches and architectures, only generally applicable considerations are provided on model development."	To be consistent with current CSV/CSA terminology and methodology.	**Proposed Addition**: Add after sentence, **"General system development lifecycle principles apply to model development and maintenance."**	Yes
301-302	PDA suggests adding requirements around vendor audit, quality agreements, etc. after the current text. **Current Text:** "…and to keep traceable documentation and development logs to allow	Clarification of manufacturer's responsibility is recommended here. Guidance is needed regarding proprietary models	**Proposed Addition**: Add after sentence, "**The use of third parties to e.g., supply, develop, customise, train, validate or maintain a model on behalf of the manufacturer, must be governed by the appropriate formal agreements. The need and level of audit required should be based on both**	Yes

	secondary assessment of development practices.”	and the use of third parties when it is not possible to keep such detailed documentation.	**the model and supplier risk. Quality risk management must address any limits to model understanding arising from the use of proprietary models and data sets.”**	
303 - 305	PDA recommends adding the proposed sentence after the text below. **Current Text:** "It is strongly encouraged that methods promoting generalisability are explored and implemented, including regularization techniques, drop-out, and sensitivity analyses with stratification of training data based on calendar time.”	In addition to the current text, freezing of AI Models is good practice (i.e., exporting it to a standard format) and could help to warrant the traceability and versioning of the AI Models.	**Proposed Addition**: Add after sentence, **“AI Models should be frozen and exported in a readable format and kept in original format throughout the lifecycle of the model as well. The use of standards is strongly recommended.”**	Yes

2.4.6 Model deployment *(lines 343-357)*

Line number(s) of the relevant text (e.g., 20-23)	Comment	Rationale for change	Proposed change	Is this a MAJOR concern/ comment? [Yes; No]
345-347	All changes must be subject to change control. PDA suggests removing “non-trivial” before “changes”. **Current Text:** “For high-risk use cases, all non-trivial changes in the software and hardware stack…”	To be consistent with current CSV/CSA terminology and methodology.	**Proposed Change**: “For high-risk use cases, **all changes** in the software and hardware stack supporting the model, including version changes for key dependencies, require a bridge re-evaluation of model performance.”	Yes

2.5 Governance *(lines 358-362)*

Line number(s) of the relevant text (e.g., 20-23)	Comment	Rationale for change	Proposed change	Is this a MAJOR concern/ comment? [Yes; No]
359-362	PDA acknowledges and agrees with the expectation for governance. However, the expectations as written are unclear, and would propose that additional guidance addressing governance related to implementing advanced algorithms be included. **Current Text:** **"**SOPs implementing GxP principles on data and algorithm governance be extended to include all data, models and algorithms used for AI/ML throughout the medicinal product lifecycle. Aspects related to the governance of all components used, the application of data protection and compliance and applicable data protection laws and ethical standards should be documented and regularly reviewed."	Although reference is made to extend existing SOPS that address GXP principles on data and algorithm governance, unique attributes of advanced algorithms require particular guidance, subjective to individual organizations and potentially unknown entirely to organizations that have not yet implemented governance of advanced algorithms.	**Proposal:** It would be helpful for the reader to define and clarify the "AI lifecycle" as the foundation for governance and describe a governance model/structure that includes expectations for oversight, roles and responsibilities, ownership and accountability, risk management, AI systems design, modeling, transparency, explainability, bias, operations, etc. as well as guide on the sentiment to utilize already effective, specific guidelines (e.g., on Risk Management).	Yes

2.6 Data protection *(lines 363-381)*

Line number(s) of the relevant text (e.g., 20-23)	Comment	Rationale for change	Proposed change	Is this a MAJOR concern/ comment? [Yes; No]
364-366	Only the EU is noted in the document. PDA suggests including reference to other customer countries at the end of the sentence. **Current Text:** "…are stored and processed in accordance with Union data protection legislation."	EMA governed companies need to also follow laws of countries outside of the EU to which they sell product.	**Proposed Change**: "It is the responsibility of the applicant or MAH to ensure that all personal data, including those indirectly held within AI/ML models, are stored and processed in accordance with Union data protection legislation **and other customer country laws as well, if applicable."**	Yes

Section 3 Conclusion *(lines 419-434)*

Line number(s) of the relevant text (e.g., 20-23)	Comment	Rationale for change	Proposed change	Is this a MAJOR concern/ comment? [Yes; No]
421-425	PDA proposes including manufacturing as one of the respective fields. **Current Text:** "…best practices are directly applicable to AI/ML and efforts should be made in all organisations to reciprocally integrate data science competence with	ML has a huge potential in GMP and supporting QMS.	**Proposed Change**: "In several aspects such as data management, governance, and statistical stringency, currently established regulatory principles, guidelines, and best practices are directly applicable to AI/ML and efforts should be made in all organisations to reciprocally integrate data science	Yes

	the respective fields within medicines development and pharmacovigilance."		competence with the respective fields **within the medicinal product lifecycle including medicines development, commercial manufacturing and pharmacovigilance."**	
431-433	PDA suggests replacing "AI" with "advanced algorithms" for consistent use of terms. **Current Text:** "Finally, the use of AI in the medicinal product lifecycle…"	Consistent use of terms.	**Proposed Change**: "Finally, the use of **advanced algorithms** in the medicinal product lifecycle should always occur in compliance with the existing legal requirements, by considering ethics and its underlying principles and with due respect of fundamental rights."	Yes

Section 4 Glossary *(lines 435-439 + terms)*

Line number(s) of the relevant text (e.g., 20-23)	Comment	Rationale for change	Proposed change	Is this a MAJOR concern/ comment? [Yes; No]
	PDA suggests considering modifying the definition of "Artificial Intelligence (AI)" in this document. "AI" is an umbrella term that comprises all different kinds of ML models – these ML models are based on (human) observed or made-up rules **casted** in lines of code, neatly executed.	The term "intelligent behaviour" should be reserved for humans. Behaviour in AI is understood in the sense of execution of software code. Self-updating of "intrinsic" parameters of a model (e.g., hyperparameters)	**Proposed Change**: "**Artificial Intelligence (AI), in the understanding as an umbrella term, constitutes a diverse set of mathematical techniques, scientific algorithms and statistical models, written in machine interpretable code, that enable computerized systems to perform specific tasks that typically require human intelligence. This includes methods covered under the term "Machine Learning", where specific algorithms mimic patterns from (large amounts of) quality data to make tasks like predictions, classifications or decisions among others, and methods covered under the term "Deep Learning", a specific type**	Yes

		is also coded in the software upfront.	**of "Machine Learning" that utilizes neural networks for complex pattern recognition."**	