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Roche feedback to the European Commission's proposed Regulation of Artificial Intelligence (the "AI Act")

F. Hoffmann-La Roche (Roche) is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Roche welcomes the opportunity to provide feedback to the European Commission's proposed regulation on Artificial Intelligence (the "AI Act") as an important step towards Europe's vision to become a global hub for trustworthy Artificial Intelligence (AI). Roche is supportive of the Commission's focused intent on trying to guarantee the safety and fundamental rights of people and businesses, while strengthening AI uptake, investment and innovation across the EU.

Roche fundamentally believes in the vast potential for AI within healthcare for patients, businesses and society at large, but also acknowledges the need to manage and mitigate any associated risks of introducing such new technologies. We believe it will therefore be very important to proportionately manage risks through this regulation and ultimately strike the right balance between preserving innovation in this sector whilst also ensuring the rights, privacy and protection of European citizens and patients.

Context for Roche Feedback

Roche's perspective on the proposed act is based on its role within the health sector and relevant to the AI/ML related projects and applications currently in development across different parts of our business. The intent is that this feedback supports considerations of a cross sectoral nature within this AI act but also be considered to support any necessary health sector specific AI frameworks expected within the provisions of the European Health Data Space (EHDS) legislative proposal due in Q1/Q2 2022.

The Commission's plans to create a single market for health data, digital services and AI in health through the creation of the EHDS promises to unlock the power of data for AI-enabled healthcare and a well-functioning EHDS should incentivise data sharing and harmonise applicable rules to remove barriers to the collective benefits across Europe. In order for all stakeholders, including providers and operators, to train, test, develop and apply a trustworthy, reliable AI system, clear rules on health data access and processing within EHDS should be laid out. To this effect Roche is also engaging in efforts to support the creation of the EHDS through direct consultations (for example the current EHDS public consultation), multi-stakeholder forum discussions, panels and workshops, and also at the national EU level through the joint action towards the EHDS (TEHDAS) lead by Sitra.

It is also important for us to note that existing EU Medical Device Regulations (Regulation (EU) 2017/745 and Regulation (EU) 2017/746) provide a targeted, sector-specific, and risk-based approach to the regulation of AI systems with a medical device intended purpose that ensures their safe and effective use. Efforts should be made to avoid the implementation of regulatory requirements that overlap and/or conflict with these Regulations. As described in our detailed comments, AI medical and in vitro diagnostic devices should be regulated in the same manner as all other medical devices, based on their intended use and according to the MDR/IVDR. Such an approach simultaneously supports speed of innovation while ensuring that safe and effective AI medical devices reach patients and healthcare professionals in an expeditious manner.

General considerations:

Within our feedback below we provide comments, suggestions and recommendations reflecting those areas we consider most important to the healthcare and health data sector, in addition to further more specific comments and legal text recommended clarifications.

At a high level for consideration within this Act, Roche's main response points are built around the following key themes:

- Roche consider the AI techniques and approaches described, including the definition of an AI system, as too general and broad in scope
    - We strongly recommend making a clearer distinction between AI driven analysis techniques and more traditional (non-AI driven) approaches to data analysis to avoid misinterpretation.

- Roche believes the proposed Act is too heavily focused on the potential risks of AI
    - We recommend a more balanced benefit risk methodology be employed when approaching the assessment of AI systems.

- Roche believes it is of paramount importance to ensure real harmonisation of the interpretation and implementation of this Act at the EU National Member state level to avoid the issues now seen with the GDPR
    - We recommend a more prescriptive approach and enforcement mechanism for the national bodies and European Artificial Intelligence Board to ensure a robust and consistent implementation of this regulation across member states.

- Roche believes that the existing Medical Device Regulation (MDR, Regulation (EU) 2017/745) and In-Vitro Diagnostic Medical Device Regulation (IVDR, Regulation (EU) 2017/746) address the identified risks of AI systems with a medical device intended purpose, and any AI-specific requirements for such devices should be managed under the existing Regulations
    - We strongly recommend that AI systems with an intended medical purpose should be excluded from the proposed AI act to avoid duplication and additional burden that could ultimately stifle innovation.

- Roche believes the proposal for national regulatory sandboxes to provide a safe and controlled environment to test innovative technologies needs more flexibility
    - If the direct supervision and guidance by national authorities is employed in a way which is too strict and controlling, it could impair innovation and be counterproductive to the aims of enabling more flexible and agile testing approaches.

- Roche believes that both the technical (interoperability) and legal barriers which hinder cross border exchange of data for AI development must be addressed
    - We recommend the Commission address both the technical and legal barriers impacting cross border exchange and scalability of health data so crucial to the development of Artificial Intelligence and Machine Learning in healthcare

- Roche believes access to high quality health data sets for training, validation and testing of AI for use in health is of paramount importance and should follow recognised standards
    - We recommend the Commission make more explicit reference to existing well recognised standards. For example, in order to implement the practices outlined in a consistent way it is important to ensure that the underlying data as a minimum meets the FAIR principles.

- Roche believes the role and interplay between the European Artificial Intelligence board (EAIB) and the European Data Protection Board (EDPB) as it relates to data governance needs further clarification
    - We support the creation of the EAIB to ensure a smooth, effective and harmonised implementation of this AI Act, however, we recommend more clarity is set out around its interplay with the EDPB related to data governance and access for the development of AI.

Specific areas of feedback and comment

AI Act Mechanism / Provision	Roche Comments and suggestions	Relevant section / text of proposed Act
AI techniques and approaches, including the definition of an AI system, are too broad and general	The range of techniques described and in scope of this Act are considered very wide and too general, to the point where one could interpret almost any system which receives data as a form of input considered in scope. This is a concern because it also means that even traditional (non-AI driven) biometric analysis of clinical data (for example standard epidemiology modelling) could be considered as in scope here. Roche believes a fundamental distinction and separation between traditional analytical approaches and AI driven approaches needs to be reflected in the description of techniques in scope of Annex 1. Such a separation could be described by focusing on the purpose of AI rather than the specific technical approach, or another element to focus on could be the "black-box" aspect and character of AI which is not an issue with traditional analytical approaches. In addition and more specifically related to software, Roche believes the current language could apply to almost any software. For example, Annex I (in conjunction with Article 3(1)) indicates that software that is developed using "statistical approaches" is an artificial intelligence system. This language is overly broad and will consequently require most software to be subject to this proposed Act. This also applies to the medical technology sector for software that is traditionally not considered to be artificial intelligence software. For example, "expert systems" have a specific meaning in the medtech sector (see Annex I of the MDCG 2019-11 guidance) and do not always leverage artificial intelligence. However, according to the definition provided in this proposed Regulation, they are always subject to its requirements. As a result, we urge the Commission to reconsider the definition of "artificial intelligence" in the context of this Regulation. While we agree that the fundamental definition of AI can include a number of forms, we propose that the Regulation focus on those AI systems that have been developed using machine learning approaches – those applications that use data to learn without being explicitly programmed. This provides a clearer definition that is more readily understood and interpretable by all stakeholders. Our suggestion is for Annex I to be modified in the following manner (deletion of b) and c)): (a) Machine learning approaches, including supervised, unsupervised and reinforcement learning, using a wide variety of methods including deep learning; (delete) (b) Logic- and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems;	Annex 1 - ARTIFICIAL INTELLIGENCE TECHNIQUES AND APPROACHES and Article 3 (definition of AI system)

	(delete) (c) Statistical approaches, Bayesian estimation, research and optimization methods.	
Ensuring a balanced assessment of both the risks and benefits of AI systems	Regarding the assessment of AI systems, the risk based approach dictates that the primary (and seemingly only) component for assessment of any AI system is that of risk (in terms of citizen safety, health and rights). We recommend greater consideration is given to the potential benefits of any given AI system, and that the overall assessment would therefore be a more balanced, ratio-based assessment similar to those e carried out in the review of medicinal products. In such cases, what drives the ultimate decision to approve a medicine is a clear assessment weighing the risks vs. the benefits with a positive benefit/risk ratio meaning the benefits are overall worth the potential and known risks. All medicinal products have a certain risk (similar to AI systems) but in each case, the fundamental assessment relies on whether the benefits outweigh those risks. Employing a similar methodology would enable a more balanced approach to the assessment of AI.	(1) "This Regulation pursues a number of overriding reasons of public interest, such as a high level of protection of health, safety and fundamental rights" (14) "In order to introduce a proportionate and effective set of binding rules for AI systems, a clearly defined risk-based approach should be followed. That approach should tailor the type and content of such rules to the intensity and scope of the risks that AI systems can generate. It is therefore necessary to prohibit certain artificial intelligence practices, to lay down requirements for high-risk AI systems and obligations for the relevant operators, and to lay down transparency obligations for certain AI systems" Article 7 point 2 "When assessing for the purposes of paragraph 1 whether an AI system poses a risk of harm to the health and safety or a risk of adverse impact on fundamental rights that is equivalent to or greater than the risk of harm posed by the high-risk AI systems already referred to in Annex III, the Commission shall take into account the following criteria: then lists lots of examples"
Ensuring Harmonisation of interpretation and implementation of the AI Act at EU National Member state levels	We believe it is imperative to avoid the issues seen with the GDPR in terms of inconsistent interpretation and implementation of an EU wide legislation at the national, cross EU member state level due to further impact on confusing legal landscapes which make it difficult for businesses to navigate (and can negatively impact investments in the areas of digital and data in Europe). The GDPR was a much needed and welcomed piece of legislation, however a fully harmonised approach to the rules on processing of data (including health data) across the EU has not been achieved. Currently, access to, sharing of, and reuse of health data for research and innovation remains fragmented. This fragmentation has recently been re-confirmed within the Commission's recent report "Assessment of the EU Member States' rules on health data in the light of GDPR" released on 11th Feb 2021. It is therefore essential to ensure uniform application and implementation of this AI act across member states to avoid confusion within the single market. However, some of the language included within the proposal is not specific enough to allow a truly uniform approach at the member state level. For example, stating "each Member State should designate one or more national competent authorities for the purpose of supervising the application and implementation of this	(2): "Certain Member States have already explored the adoption of national rules to ensure that artificial intelligence is safe and is developed and used in compliance with fundamental rights obligations. Differing national rules may lead to fragmentation of the internal market and decrease legal certainty for operators that develop or use AI systems. A consistent and high level of protection throughout the Union should therefore be ensured" (77): "Member States hold a key role in the application and enforcement of this Regulation. In this respect, each Member State should designate one or more national competent authorities for the purpose of supervising the application and implementation of this Regulation. In order to increase organisation efficiency on the side of Member States and to set an official point of contact vis-à-vis the public and other counterparts at Member State and Union levels, in each Member State one national authority should be designated as national supervisory authority"

	Regulation" without specifying a unified process and approach to identifying and designating such a CA across the EU (or aligning on consistent capabilities of staffing within such CAs) could lead to gaps in the application and enforcement of this Regulation. We recommend a more prescriptive approach be described and employed to ensure a consistent management and enforcement of this regulation in the EU. We do acknowledge the role of the European Artificial Intelligence Board here as a board that will aim to help facilitate a smooth, effective and harmonised implementation of this act, but the finer details on how it will be enforced are currently lacking.	(84) "Member States should take all necessary measures to ensure that the provisions of this Regulation are implemented, including by laying down effective, proportionate and dissuasive penalties for their infringement. For certain specific infringements, Member States should take into account the margins and criteria set out in this Regulation. The European Data Protection Supervisor should have the power to impose fines on Union institutions, agencies and bodies falling within the scope of this Regulation" (86) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council"
AI systems with a medical device intended purpose should be excluded from the proposed act with clarifying language added to ensure that AI-related requirements for medical and in vitro diagnostic devices are harmonized under the MDR (Regulation (EU) 2017/745) and the IVDR (Regulation (EU) 2017/746)	Existing EU Medical Device Regulations (MDR and IVDR) were developed to be technology agnostic and regulate devices based on their intended use. These Regulations, especially in combination with the GDPR, already provide a targeted, sector-specific, and risk-based approach to the regulation of AI systems with a medical device intended purpose that ensures their safe and effective use. Further, the requirements the Regulations espouse in areas such as risk management, quality system management, technical documentation, cybersecurity, transparency and information to users, accuracy and robustness, economic operators, and postmarket surveillance are more extensive and often much more detailed than those described in the proposed AI act. For example, one must simply compare the General Safety and Performance Requirements (Annex I) and Technical Documentation requirements (Annex II) of the MDR/IVDR to the Technical Documentation requirements (Annex IV) of the proposed AI act to identify the robustness of the medical device requirements and their significant overlap with those of this proposed AI act. Given that most AI medical devices will be considered "high risk" under the proposed AI act, such duplication in requirements will result in significant and unnecessary additional burden for the medical and in vitro diagnostic device industry. Under the current proposal, AI medical devices will need to undergo a conformity assessment with respect to both the proposed AI act and the MDR/IVDR, and manufacturers may be required to develop two sets of technical documentation. Further, parallel incident reporting communications will be required, and AI medical device manufacturers will likely need to comply with two different sets of harmonized standards and related guidance documents. There are a number of other duplications that will lead to unnecessary burdens on AI medical device manufacturers, and this will stifle innovation in the EU and prevent patients and healthcare professionals from receiving timely access to safe, effective, and innovative technologies.	(30) As regards AI systems that are safety components of products, or which are themselves products, falling within the scope of certain Union harmonisation legislation, it is appropriate to classify them as high-risk under this Regulation if the product in question undergoes the conformity assessment procedure with a third-party conformity assessment body pursuant to that relevant Union harmonisation legislation. In particular, such products are machinery, toys, lifts, equipment and protective systems intended for use in potentially explosive atmospheres, radio equipment, pressure equipment, recreational craft equipment, cableway installations, appliances burning gaseous fuels, medical devices, and in vitro diagnostic medical devices Annex IV technical documentation referred to in Article 11(1)

	As such, we recommend that medical and in vitro diagnostic devices are explicitly excluded from the scope of this act and that clarifying language is added to ensure that AI-related requirements for medical devices are harmonized under the existing Medical Device Regulations. There are a number of regulatory mechanisms by which such an approach can be achieved, such as through the publication of an AI-focused implementing act under the MDR/IVDR, the publication of an AI-specific guidance for medical and in vitro diagnostic devices, and/or the recognition of an AI-focused harmonized standard under the MDR/IVDR. Such approaches provide a viable alternative to the duplicitous and burdensome regulatory framework that will be realized if medical devices are subject to the proposed AI act and would provide a cohesive set of requirements for AI medical devices within the context of their established regulatory framework. This, in turn, would support speed of innovation and enable safe and effective AI medical devices to reach patients and healthcare professionals in a timely manner. Our specific proposal is to include within Article 2 ("Scope") the following statement and to exclude from Annex II, Section A the Medical Device Regulations: Add to Article 2: "This Regulation shall not apply to AI systems that are safety components of products or systems, or which are themselves products or systems, falling within the scope of Regulation (EU) 2017/745 and Regulation (EU) 2017/746. For such AI systems, specific requirements are managed within the framework of those Regulations. Once the marking has been obtained, such products or systems, having regard to that function, may be placed on the market and circulate freely in the European Union without having to undergo any additional procedure." Delete from Annex II, Section A: (delete) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1;) (delete) Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).	
The availability of Notified Bodies to conduct conformity assessments and additional requirements	The number of Notified Bodies available to conduct conformity assessments according to the MDR and IVDR is quite limited, leading to enormous bottlenecks in device manufacturers being able to commercialize products under these Regulations. When the AI act is finalized, medical and in vitro diagnostic device Notified Bodies will also need to be designated under these new requirements.	Chapter 4 (NOTIFYING AUTHORITIES AND NOTIFIED BODIES)

	Despite the identified need for notified body capacity to be progressively ramped up over time, this could again lead to bottlenecks and significant delays for medical and in vitro diagnostic devices that leverage AI. As such, a pragmatic solution that enables Notified Bodies to be designated under the AI act in an expeditious manner and in alignment with MDR/IVDR requirements is needed.	
The proposal for national regulatory sandboxes to provide a safe and controlled environment to test innovative technologies needs to be more flexible	We appreciate the Commission thinking through how to create opportunities and a safe environment to develop and test innovation. However we see two issues which need to be considered: If regulatory sandboxes are intended to be implemented at the national level, this may be counterproductive to the development of AI systems that generally benefit from large-scale, broadly representative data. We therefore encourage the Commission to think about mechanisms here to avoid issues with development, validation or later wide-scale deployment of solutions of EU market-wide AI systems. In addition, while developing AI solutions under "the direct supervision and guidance" (Art. 53 1.) of authorities and in cooperation with them "following their guidance" could impair innovation and be counterproductive to the aims of enabling more flexible and agile approaches, especially given no real risk for natural persons exist as sandboxes are for development, testing and validation only (i.e. prior to go-live). We recommend wording that reflects a less prescriptive oversight in terms of supervision and guidance from the authorities to allow a more agile testing ground and process.	5.2.5 Title V contributes to the objective to create a legal framework that is innovation-friendly, future-proof and resilient to disruption. To that end, it encourages national competent authorities to set up regulatory sandboxes and sets a basic framework in terms of governance, supervision and liability. AI regulatory sandboxes establish a controlled environment to test innovative technologies for a limited time on the basis of a testing plan agreed with the competent authorities. (72) and Art. 53 - regulatory sandboxes
Both technical (interoperability) and legal barriers which hinder cross-border exchange of data for AI development must be addressed	Interoperability at all established levels (technical, syntactic, semantic, organisational) is a critically important aspect within the health sector. It could bring key benefits to health related data ecosystems, for example by facilitating seamless communications among healthcare providers and with patients throughout a patient's care pathway, which can help create longitudinal patient data. It also provides the right information to the right person, at the right time, to improve patient care and outcomes. Interoperability is also a foundational enabler for Artificial Intelligence and Machine Learning in healthcare also aimed at optimizing patient care e.g. Interoperable RWD can be generated by and leveraged in large scale national and international observational studies, which would support and accelerate research and innovation. AI-based applications rely heavily on access to quality, accurate, representative, and interpretable datasets that follow standardized formats for training, validation, and testing purposes. Therefore, the current fragmented data landscape and lack of interoperable health systems severely limit realizing the true power of AI. As such, it will be vital that the EHDS overcome these data infrastructure limitations so that the true potential of AI can be realized.	(81) “The Commission may develop initiatives, including of a sectorial nature, to facilitate the lowering of technical barriers hindering cross-border exchange of data for AI development, including on data access infrastructure, semantic and technical interoperability of different types of data”

	We therefore appreciate the Commission's aims to address the technical barriers hindering cross border exchange of data but would also appreciate if efforts could be made to address legal barriers too as national and even within country barriers in addition to regional barriers for data exchange exist (in particular for personal data)	
The role of the European Artificial Intelligence board (EAIB) and its connection with the European Data Protection Board (EDPB) needs further clarification	We support the set up of an EAIB however find it unclear how this board will interact with the EDPB and if the relationship between the two may cause confusion over responsibilities, especially given data governance is such a fundamental part of the development and use of AI. The act states that the EAIB will consult the EDPB on certain topics but broader questions remain as to the relationship between the two e.g. will they periodically meet, could the membership at member state level be the same on both boards and who will take final decisions related to access to data for the development of AI.	5.2.6: "Title VI sets up the governance systems at Union and national level. At Union level, the proposal establishes a European Artificial Intelligence Board (the 'Board'), composed of representatives from the Member States and the Commission. The Board will facilitate a smooth, effective and harmonised implementation of this regulation by contributing to the effective cooperation of the national supervisory authorities and the Commission and providing advice and expertise to the Commission. It will also collect and share best practices among the Member States." (76) "In order to facilitate a smooth, effective and harmonised implementation of this Regulation a European Artificial Intelligence Board should be established. The Board should be responsible for a number of advisory tasks, including issuing opinions, recommendations, advice or guidance on matters related to the implementation of this Regulation, including on technical specifications or existing standards regarding the requirements established in this Regulation and providing advice to and assisting the Commission on specific questions related to artificial intelligence."
Access to high quality health data sets for training, validation and testing of AI for use in health is of paramount importance and should follow FAIR principles	Roche believes data quality is an integral element in realizing the quality of care for patients and health system sustainability. In particular, access to high quality data can help enable the full potential of Personalised Healthcare (PHC) in numerous ways, including being foundational to tools and solutions used in healthcare that deploy or are based in Artificial Intelligence/Machine Learning (AI/ML), in addition to contributing to effective deployment of Clinical Decision Support tools. Health systems can also leverage quality data to measure the effect of various quality improvement interventions or programs, to ensure appropriate adoption. Roche is committed to working with health systems in defining a set of data quality principles, and educating data partners on their use and value as a foundational requirement for data ecosystems. Accessibility of high-quality data and the ability to generate insights from those data are critical steps towards enabling personalised healthcare, improving both treatments and outcomes for patients, and contributing to overall healthcare system	(44) "High data quality is essential for the performance of many AI systems, especially when techniques involving the training of models are used, with a view to ensure that the high-risk AI system performs as intended and safely and it does not become the source of discrimination prohibited by Union law. High quality training, validation and testing data sets require the implementation of appropriate data governance and management practices. Training, validation and testing data sets should be sufficiently relevant, representative and free of errors and complete in view of the intended purpose of the system. They should also have the appropriate statistical properties, including as regards the persons or groups of persons on which the high-risk AI system is intended to be used. In particular, training, validation and testing data sets should take into account, to the extent required in the light of their intended purpose, the features, characteristics or

	sustainability. With the emergence of new technologies such as digital tools, one of the requirements to realize the full value and benefit of these tools is for these data to be of sufficient quality. Thus, there is a clear need to have a defined set of data quality principles to guide data sources towards a minimum level of fit-for-purpose usability. The FAIR principles published in 2018 describe a well-organized state of data that enable it to be readily and widely used for generating scientific insights and driving more informed clinical decisions. Roche is committed to building on the FAIR data principles and driving a set of quality standards across the healthcare ecosystem to enable insightful and responsible use of data. We uphold this commitment through the following principles: Accuracy, Consistency, Completeness, Timeliness, and Interpretability, and we recommend the Commission explicitly state these principles within the act. For example it is noted that in Article 10 (Data and Data Governance), there is no specific mention of FAIR data principles or other data quality measures, but in order to implement the practices outlined it is important to ensure that the underlying data is FAIR and of a high enough quality.	elements that are particular to the specific geographical, behavioural or functional setting or context within which the AI system is intended to be used. In order to protect the right of others from the discrimination that might result from the bias in AI systems, the providers should be able to process also special categories of personal data, as a matter of substantial public interest, in order to ensure the bias monitoring, detection and correction in relation to high-risk AI systems" (45) "For the development of high-risk AI systems, certain actors, such as providers, notified bodies and other relevant entities, such as digital innovation hubs, testing experimentation facilities and researchers, should be able to access and use high quality datasets within their respective fields of activities which are related to this Regulation.
It must be recognised that "completeness" of data within certain sectors (including the health sector) can be difficult to attain and should therefore not be a strict requirement	Completeness of data may not be always fully attainable across all sectors and all data types due to the inherent nature, nuances and limitations of how data are captured and collected, therefore this act needs to allow some flexibility around this concept. In the health sector, the completeness of data can be influenced by variations in routine clinical care based on regional or disease specific variations. For example, in oncology it is well known that performance status (such as the Eastern Cooperative Oncology Group (ECOG)), is often not well maintained in Electronic Medical Records (EMR), and this causes structured missingness that is due to the nature of the collected data. In such cases, it would not be feasible to conduct prospective data collection, rather, the developers need to be aware of the limitations and implications for training, validation and testing, and need to take appropriate account in the design of the AI systems. In addition, the health sector can commit to being transparent on the measures taken to assure or describe the representativeness of the variance and variables in the training data assumed to be relevant for the deployment population, but completeness cannot really be shown to be "sufficient", as it is often simply unknowable. Trained models will always suffer when unforeseen, rare cases occur, and it seems unfeasible to require all of these scenarios to be thought through. It is also important to note that the proposed wording would likely prevent the use of Real World Data, which has huge potential for advancing healthcare. As such, we recommend that Article 10(3) is modified in the	(44) "Training, validation and testing data sets should be sufficiently relevant, representative and free of errors and complete in view of the intended purpose of the system"

	following manner: "Training, validation and testing data sets shall be relevant, and representative of the intended purpose ~~free of errors and complete~~."	
The potential for leakage of data from training sets to validation or testing sets must be avoided	Particular care should be given to ensuring that there is no data leakage from training sets to validation or testing sets when evaluating the performance of an AI system, as such data leaks can inadvertently occur if complex modelling processes are being followed. The splitting of data into training, validation, test sets should be carefully considered to maximise the external validity being demonstrated by the AI system. Multiple external validation data sets collected from different sources give a higher level of confidence than when the training and validation sets are generated as a random split of the same data set, only giving a measure of internal validity within that one dataset. We recommend the Commission consider wording to address and account for this within the regulation.	(44) "Training, validation and testing data sets should be sufficiently relevant, representative and free of errors and complete in view of the intended purpose of the system. They should also have the appropriate statistical properties, including as regards the persons or groups of persons on which the high-risk AI system is intended to be used. In particular, training, validation and testing data sets should take into account, to the extent required in the light of their intended purpose, the features, characteristics or elements that are particular to the specific geographical, behavioural or functional setting or context within which the AI system is intended to be used. In order to protect the right of others from the discrimination that might result from the bias in AI systems, the providers should be able to process also special categories of personal data, as a matter of substantial public interest, in order to ensure the bias monitoring, detection and correction in relation to high-risk AI systems"
Access to Training Data	The proposed act requires AI developers to provide Notified Bodies and postmarket surveillance authorities full access to training datasets. This may not be possible in a number of scenarios. For example, manufacturers may not have direct access to training data if the AI system has been developed using federated learning. There may also be copyright or privacy restrictions regarding training data sets. As such, we recommend that this requirement is removed from the proposed AI act. Regulatory authorities should have access to test data sets, as these are necessary to provide objective evidence of the AI system performance.	Article 64 and Annex VII
Entry into Force and Application	The MDR/IVDR experience has demonstrated that an adequate amount of time is necessary to ensure that the entire ecosystem is prepared for a regulatory transition. This includes time to ensure the publication of supporting guidance documents and implementing/delegating acts, sufficient Notified Body capacity and preparedness, and manufacturer readiness. Given the number of elements that need to be in place to ensure a successful transition, we recommend that the transitional period is extended to 48 months following the entering into force of the Regulation.	Article 85

Learning system assessments	Many AI tools and systems will be "learning systems" i.e. continuously learning, evolving systems rather than products and solutions fixed in time. There is therefore a need and expectation for continuous data additions to improve performance, and the need for continuous AI iteration related assessments in time that have to be considered, along with the methods and criteria to assess them. This evolving nature has not been sufficiently covered in this proposal	N/A – recommended area of focus not discussed in the proposed Act
Education of domain specialists	Specific to healthcare, multiple roles within the healthcare system will be impacted by the development and deployment of AI. Some, for example clinicians, cannot be expected to keep up with the fast developments and deeper inner workings of AI systems (e.g. correlation vs causality), bringing up the need for education of benefits and limitations of these tools, to eliminate fear, mistrust or scepticism, in addition to being clear on the aspect of augmented results by an AI system plus human judgement, vs AI alone.	N/A – recommended area of focus not discussed in the proposed Act

Miscellaneous/other comments, clarifications and recommendations including those of a legal nature

AI Act Mechanism / Provision	Roche Comments and suggestions	Relevant section / text of proposed Act
Social scoring of patient health status	Scoring of patient health status in comparison to their community could help motivate and improve overall patient outcomes. Clarification of beneficial scoring with examples may help this section	(21) "AI systems providing social scoring of natural persons for general purpose by public authorities or on their behalf may lead to discriminatory outcomes and the exclusion of certain groups. They may violate the right to dignity and non-discrimination and the values of equality and justice. Such AI systems evaluate or classify the trustworthiness of natural persons based on their social behaviour in multiple contexts or known or predicted personal or personality characteristics. The social score obtained from such AI systems may lead to the detrimental or unfavourable treatment of natural persons or whole groups thereof in social contexts, which are unrelated to the context in which the data was originally generated or collected or to a detrimental treatment that is disproportionate or unjustified to the gravity of their social behaviour. Such AI systems should be therefore prohibited."
Usage of biometric samples to match patient data in public spaces	It may be helpful to clarify if this prohibits usage of biometric samples to match patient data in public spaces (e.g. hospitals) in real time before treatment or diagnostic procedure.	(21) "The use of AI systems for 'real-time' remote biometric identification of natural persons in publicly accessible spaces for the purpose of law enforcement is considered particularly intrusive in the rights and freedoms of the concerned persons, to the extent that it may affect the private life of a large part of the population, evoke a feeling of constant surveillance and indirectly dissuade the exercise of the freedom of assembly and other fundamental rights."

Process for Defining high risk AI systems	Certain areas where AI plays a role may be high risk by nature of the process (e.g. hazardous material, diseases). Suggest wording to differentiate "high-risk" when AI reduces such risk but continues to pose some risks. It may be better to look at the role of AI in increasing risk of harm for individuals as a "high-risk".	(3) "The proposal lays down a solid risk methodology to define "high-risk" AI systems that pose significant risks to the health and safety or fundamental rights of persons
Reliability and accuracy in health diagnostics	Absolute reliability/accuracy are ambiguous terms in this context. In health applications the existing human intelligence is certainly far from reliable and accurate. We recommend amending the wording to state that increasingly sophisticated diagnostics systems and systems supporting human decisions should "offer demonstrable additional medical benefit compared to care in the absence of the AI". It could also be considered to add wording to highlight that the performance and boundary conditions of the algorithms should be well understood and accounted for in the implementation to ensure a positive benefit/risk profile in use.	P.25(28) "Similarly, in the health sector where the stakes for life and health are particularly high, increasingly sophisticated diagnostics systems and systems supporting human decisions should be reliable and accurate"
Additional definitions	We believe it would be important to add additional definitions for important key terms such as high-risk, transparency and benefit. For example for the term high-risk, it appears 286 times in the legal text but is more in reference and around. The decision-making and definition of what qualifies as high-risk is critical.	Article 3
Legal persons	Stating that there are high risks to legal persons is inconsistent with the general approach that the Regulation shall protect natural persons. To avoid confusion, we recommend deleting "legal persons".	(37) 2nd last sentence: Nonetheless, this Regulation should not hamper the development and use of innovative approaches in the public administration, which would stand to benefit from a wider use of compliant and safe AI systems, provided that those systems do not entail a high risk to legal and natural persons.
Legal ground for processing of personal data	Considering recital (44), it is unclear whether or not the situations described in Art. 10 5. and 54 1. a) would be a legal basis for personal data processing. A clarification that personal data processing mentioned in the two articles are justified and a legal basis in accordance with GDPR. We recommend a clarification here.	(41), (44), Art. 10 5., Art. 54 1. a) [(41)]: This Regulation should not be understood as providing for the legal ground for processing of personal data, including special categories of personal data, where relevant.
Personal non-professional activity	It is unclear what "personal non-professional activity" in this context means, we recommend providing clarification.	(59 It is appropriate to envisage that the user of the AI system should be the natural or legal person, public authority, agency or other body under whose authority the AI system is operated except where the use is made in the course of a personal non-professional activity
Privileges for small-scale providers	Privileges for "small-scale providers" could be seen as discriminating by some considering their activities may cause the same risks for natural persons as any AI system developed or used by larger entities. This could be addressed in the proposed regulation	(73) and Art. 55: small-scale providers
Biometric Classification data	Hair colour, eye colour and tattoos are not considered biometric classicisation data. These are rather attributes which can be deduced from data collected for biometric recognition purposes. We recommend specifying this or	Art. 3 (35) biometric categorisation system

	deleting those items not considered as biometric data	
Record keeping retention time	We recommend defining a specific retention time for clarity	Art. 12 Record-keeping
Reasons to consider AI use presenting a risk	The wording "have reasons to consider" is vague and requires further clarification and description, especially considering the potential penalties involved.	Art. 29 4. When [users] have reasons to consider that the use in accordance with the instructions of use may result in the AI system presenting a risk within the meaning of Article 65(1) they shall inform the provider or distributor and suspend the use of the system.
Notifications once provider has established a causal link between AI system and incident or malfunctioning or the reasonable likelihood of such a link	We consider the 15 day notification period as reasonable. However with consideration to the required 72 hours for personal data breaches according to GDPR, we wonder what this means if a GDPR breach and an AI Regulation breach occur at the same time. In such scenarios of a breach in both regulations we would consider two notifications unnecessary and redundant and therefore suggest that a notification under the AI regulation is not necessary if a notification was or has be done under any other EU law.	Art.62 1. Such notification shall be made immediately after the provider has established a causal link between the AI system and the incident or malfunctioning or the reasonable likelihood of such a link, and, in any event, not later than 15 days after the providers becomes aware of the serious incident or of the malfunctioning.
AI system compliance with EU AI regulation vs national laws	It remains unclear and vague as to why member state authorities should challenge a system that complies with the EU regulation. Such a concept will challenge the common market approach of the EU and could lead to uncertainty and negatively impair EU market dynamics.	Art. 67 1. Where, having performed an evaluation under Article 65, the market surveillance authority of a Member State finds that although an AI system is in compliance with this Regulation, it presents a risk to the health or safety of persons, to the compliance with obligations under Union or national law intended to protect fundamental rights or to other aspects of public interest protection, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk, to withdraw the AI system from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.