Congenius

AI in MedTech series:

Managing your AI model submission

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For traditional AI, it's important to properly understand the reality an AI model is supposed to represent, to understand which are the relevant factors and aspects of this reality, and to create a model accordingly.

If the traditional AI model is unsuitable to represent this reality, it's not possible to train the model such that its output will be sufficiently credible. Whilst this is not the case for deep networks and other certain types of very complex AI models, it's nevertheless important to understand the structure and algorithms of such models.

Therefore, explaining the architecture of your AI model with the respective learning algorithm and justification for the chosen architecture, including the methods used to develop the model, is an essential part of any submission for an MDAI and key for the regulatory authority's submission file review.

In the following pages, our Head of eHealth Dr. Dirk Hüber will share the key considerations to bear in mind before submission, and a useful overview of the required submission documents.



Important considerations before submission

When incorporating an AI model into your medical device, it is important to:

- ✓ **Evaluate the feasibility** of managing the model and documentation updates
- ✓ **Assess available information** about the model while understanding how information gaps may impact safety
- ✓ **Implement appropriate risk controls**, such as human oversight and guardrails, as well as those that may be needed for model deployment

Data relevancy

Even when information is available on the training data set, manufacturers may find that general-purpose models are typically not trained on data that is representative of the intended use population or clinical use case. In this case, methods such as transfer learning and fine tuning can be used as part of a comprehensive risk strategy to address these representativeness gaps.

Emergent behaviours

For generative AI-enabled models, it is also important to monitor for emergent behaviours or unintended content generation over time as the model or its environment changes.



Important considerations before submission

Leveraging general-purpose and off-the-shelf models

Providing transparent information about the use of general-purpose and off-the-shelf models is important for both regulatory authorities and users to understand the foundation, reliability, and limitations of an AI-enabled device that incorporates these types of models.

Manufacturers choosing to incorporate or leverage third-party, general-purpose models, including large language models (LLMs), other architectures, or foundation models into their AI-enabled medical devices, should:

- ✓ Implement **robust supplier management practices** and follow industry best practices for software of unknown provenance (SOUP) and third-party oversight
- ✓ Evaluate the **third-party supplier credibility**, model **provenance**, model's **longevity**, and life cycle management processes, including the model's **version history**, **update cadence**, and **support commitments**
- ✓ Assess and document the model's known **limitations**, **potential biases**, and **uncertainties**
- ✓ Understand the generative behaviour of the model, such as **variability in outputs**, **susceptibility to hallucination**, and **dependence on input prompts or context**



What submission documents should be provided?



Model Development & Maintenance Plan



Model Description



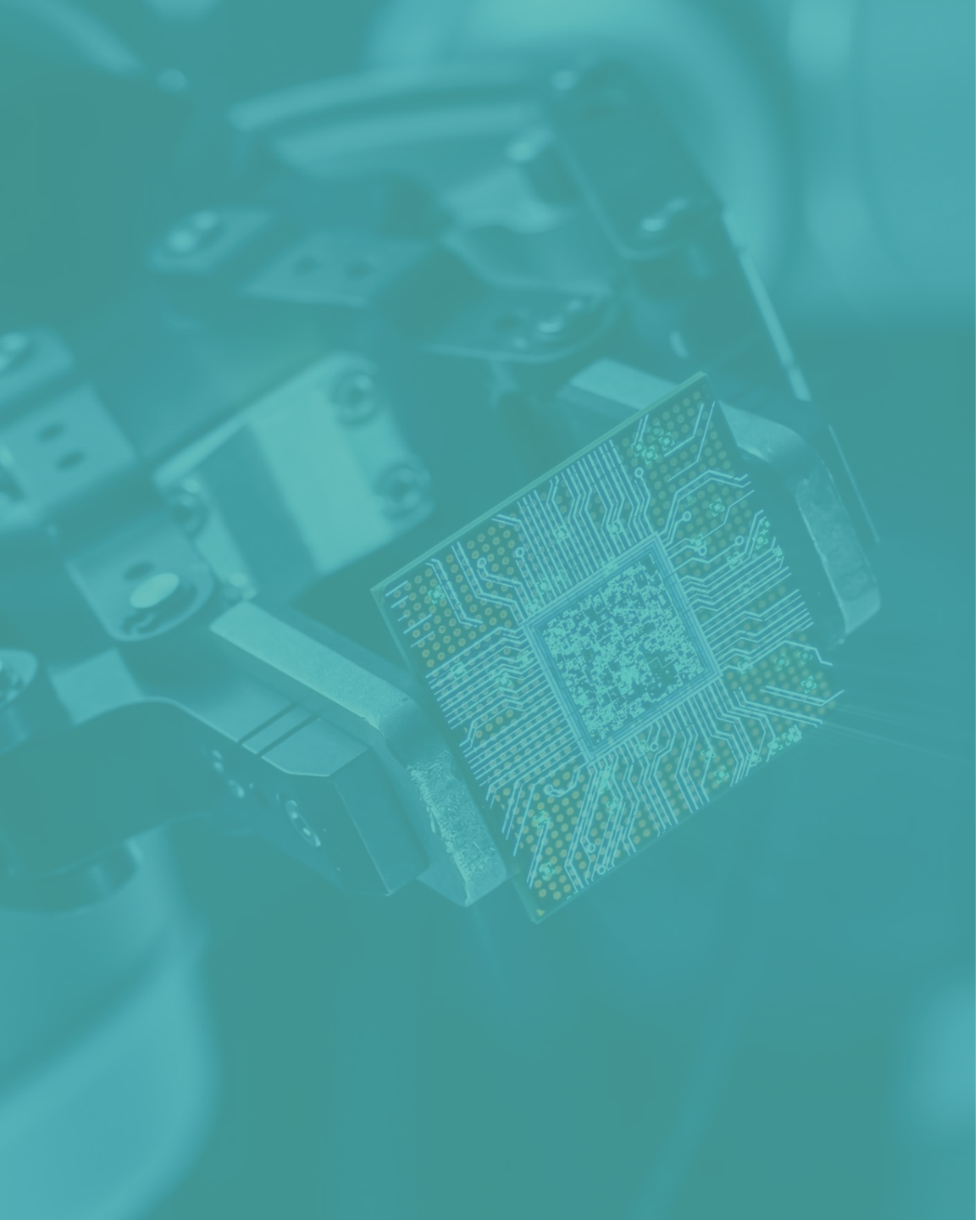
Model Development Report



Model Development & Maintenance Plan

The Model Development & Maintenance Plan plans all activities necessary to develop and maintain the MDAI including:

- Establishing credibility
- Assessing your AI model
- Submission documentation
- Training, Tuning, Validation
- Data
- Bias
- AI software engineering & lifecycle management
- Risk management
- Cybersecurity
- Usability
- Human oversight
- Sociotechnical aspects
- Transparency
- Performance validation & clinical evidence strategy
- Predetermined change management
- Post-Market Surveillance & performance monitoring



Model Description

The Model Description covers:

- **Model inputs and outputs**, i.e., which input does the model require from a user to answer the Question of Interest, and which output will the model provide to the user. Model inputs also include the data sets used for training, tuning, and validation
- **A description of model architecture**, e.g., applied technique and algorithm (e.g., state space search, local search, formal logic, probabilistic methods, classifiers, statistical learning methods, neural networks, deep learning, GPT)
- **A description of features**
- **A description of the feature selection process** and any loss function(s) used for model design and optimisation, as appropriate
- **Model parameters** (e.g., weights and vectors), including non-learnable parameters and options for customisation (hyperparameters)



Model Development Report

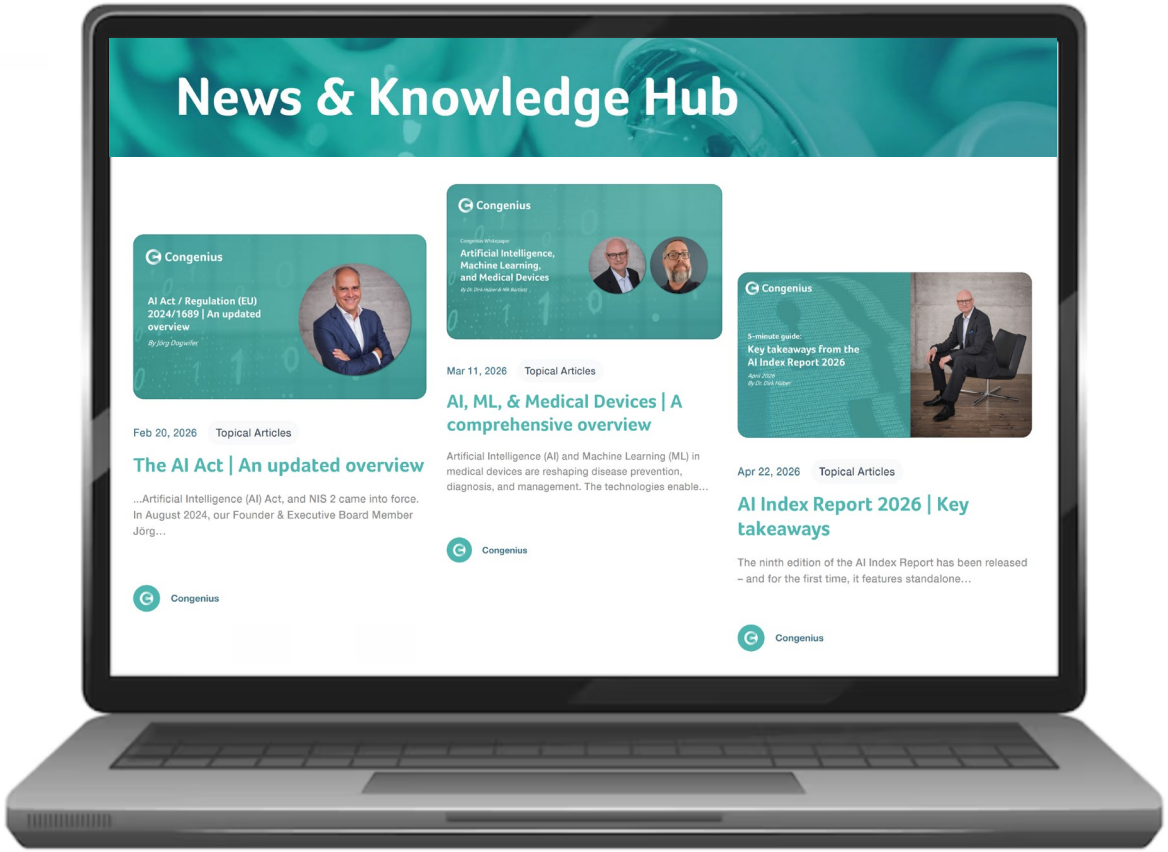
The Model Development Report covers development topics that are specific to AI, i.e., how the model has been trained and tuned and with which outcome:

- Information on the data used to train, tune, and validate the MDAI and how data requirements are met, including respective quality control measures
- Information on how the requirements for training, tuning, and validation are met, including but not limited to:

✓ Optimisation methods
✓ Training paradigms
✓ Regularisation techniques employed
✓ Training hyperparameters
✓ Summary of training performance
✓ If tuning evaluation was conducted, a description of the metrics and results obtained
✓ An explanation of any pre-trained models that were used, as applicable
✓ If a pre-trained model was used, specify the dataset that was used for pre-training and how the pre-trained model was obtained (a previous version of the AI model also counts as a pre-trained model)
✓ A description of the use of ensemble methods as applicable
✓ An explanation of how any thresholds were determined
✓ An explanation of any calibration of the model output

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Do you have an MDAI challenge?
Contact our experts to start the conversation,
or to request your free copy of our AI Handbook.

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