# AI Algorithmic Auditing and Dataset Testing (AA&DT) for the Medical Imaging Industry

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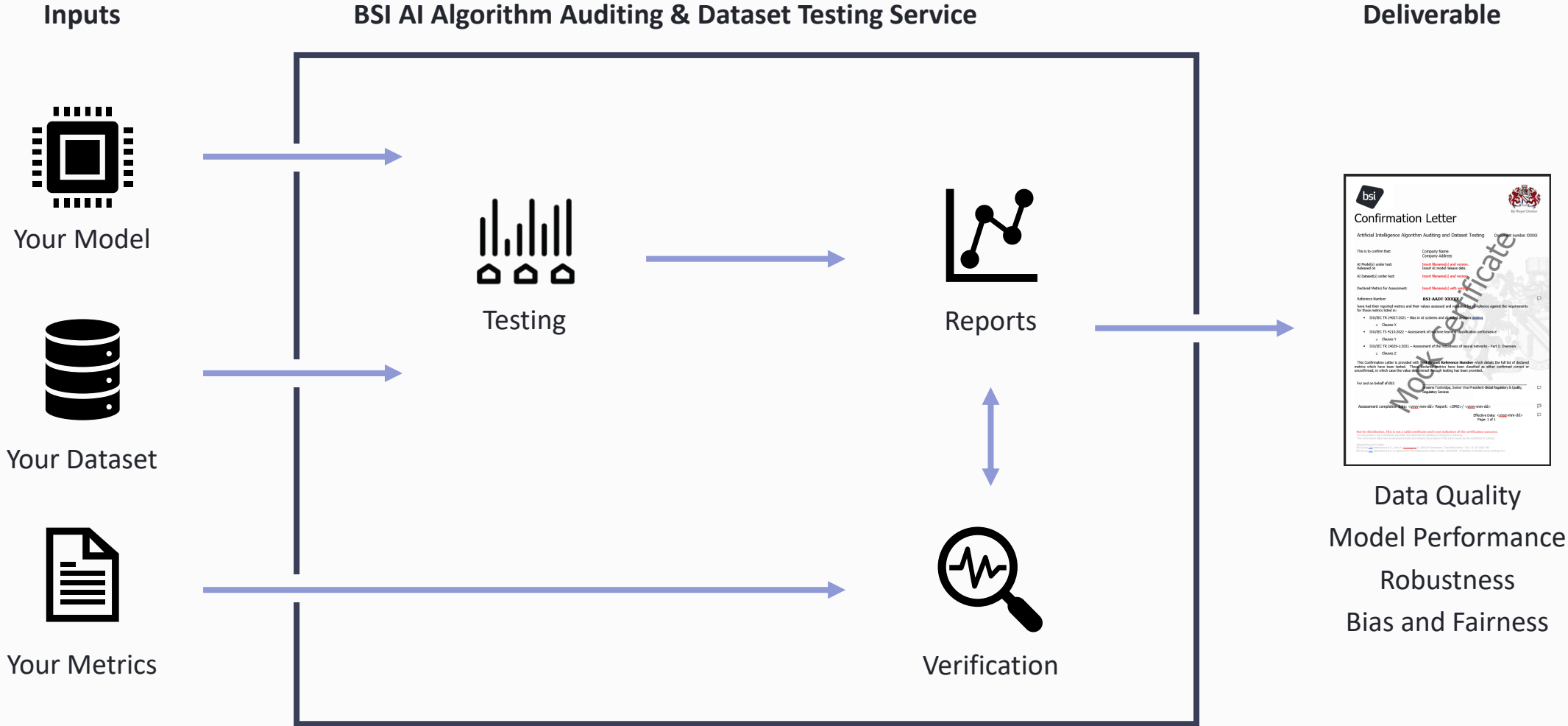
**16 January 2025**

# Agenda

# What is AI AA&DT?

**Inputs**

**BSI AI Algorithm Auditing & Dataset Testing Service**

**Deliverable**

Your Model

Your Dataset

Your Metrics

Testing

Reports

Verification

Data Quality

Model Performance

Robustness

Bias and Fairness

# Poll question

# Supplying your Models and Datasets

Your models and datasets will be uploaded, stored and deleted securely

- BSI offer a secure upload service via our portal or SFTP

- Your dataset and model are temporarily stored during the assessment on secure servers, based in the EU

- Following the assessment your dataset and model will be securely deleted, with a deletion certificate

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# Supported AI workflows

BSI supports common AI workflows, is expanding the supported range, and would like to hear of your needs and feedback

- BSI currently supports AI workflows including classification, object detection and semantic segmentation

- Additional workflows are under development, including biometric identification and verification

- Please speak with us to discuss your needs
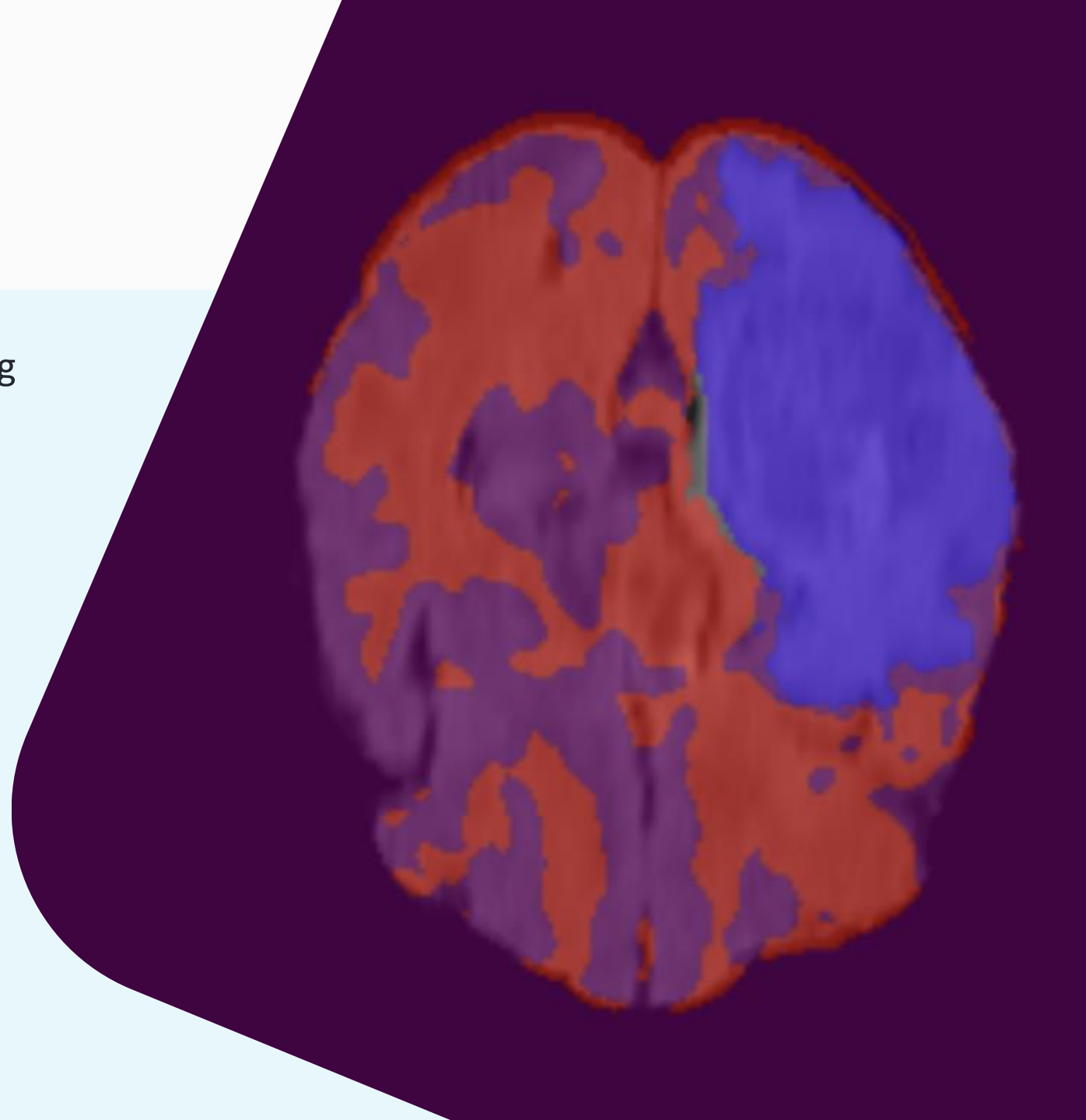
# Supported AI metrics

BSI supports common metrics appropriate to supported AI workflows, based on international AI standards

- Supported metrics are derived from ISO/IEC standards including:
    - ISO/IEC 4213:2022 (Classification Performance)
    - ISO/IEC 24027:2021 (Bias and Fairness)
    - ISO/IEC 24029-1:2021 (Robustness)
    - ISO/IEC 3532-2:2024 (Segmentation Performance)
- Includes common metrics for classification, object detection and segmentation workflows, e.g.
    - Confusion matrices, accuracy, precision, recall, sensitivity, specificity, F1, ROC curves…
    - Dice coefficient, Hausdorff distance…
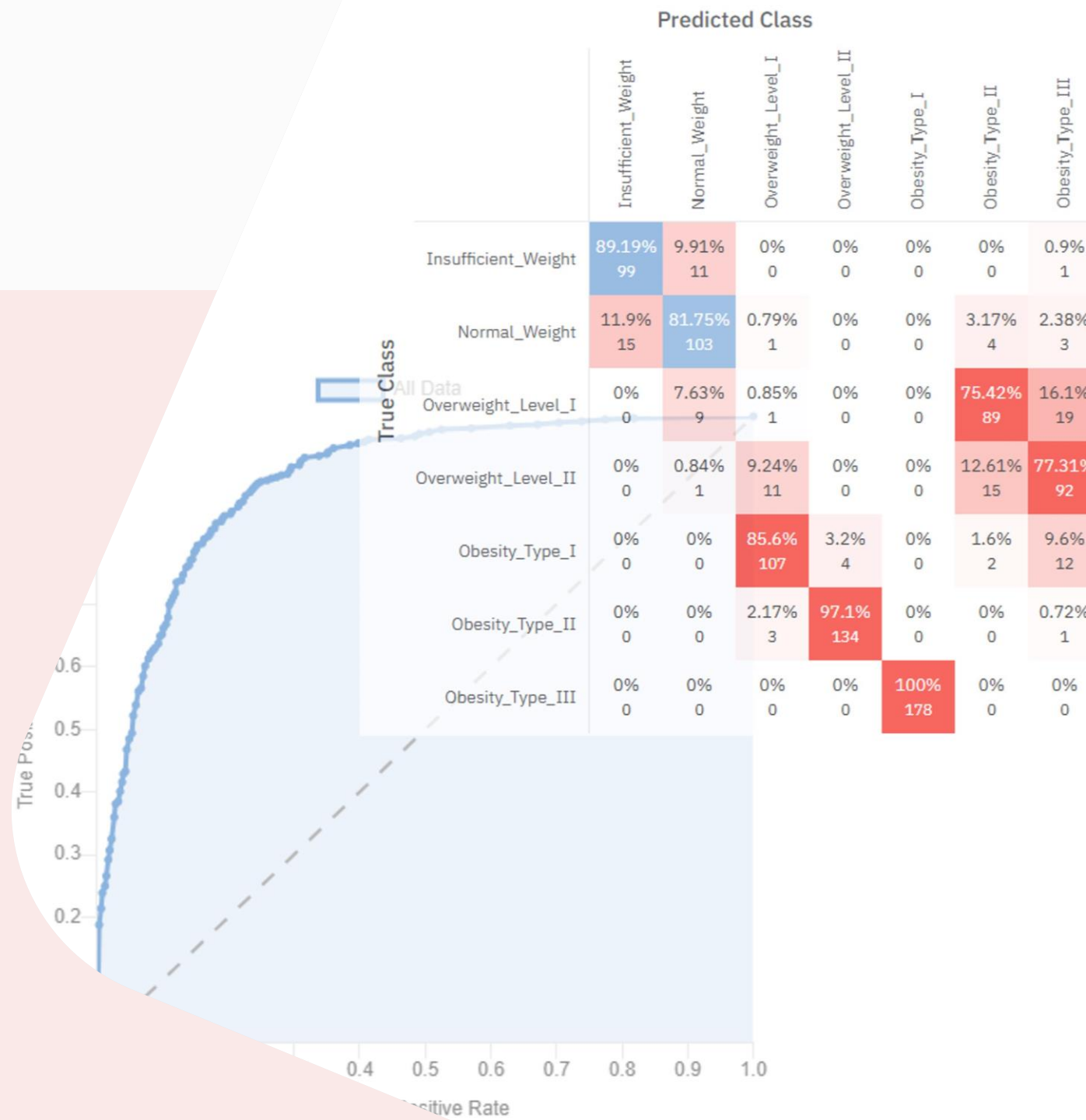
# Supported dataset and model formats

BSI supports common dataset and model formats, model-neutral formats, and model-free assessments

- Tabular – CSV, parquet

- Image – JPG, PNG, DICOM 2D/3D, NIFTI

- Docker, Python code, common model formats such as PyTorch, TensorFlow/Keras, scikit-learn, XGBoost

- Precomputed predictions – no model supplied, just model predictions

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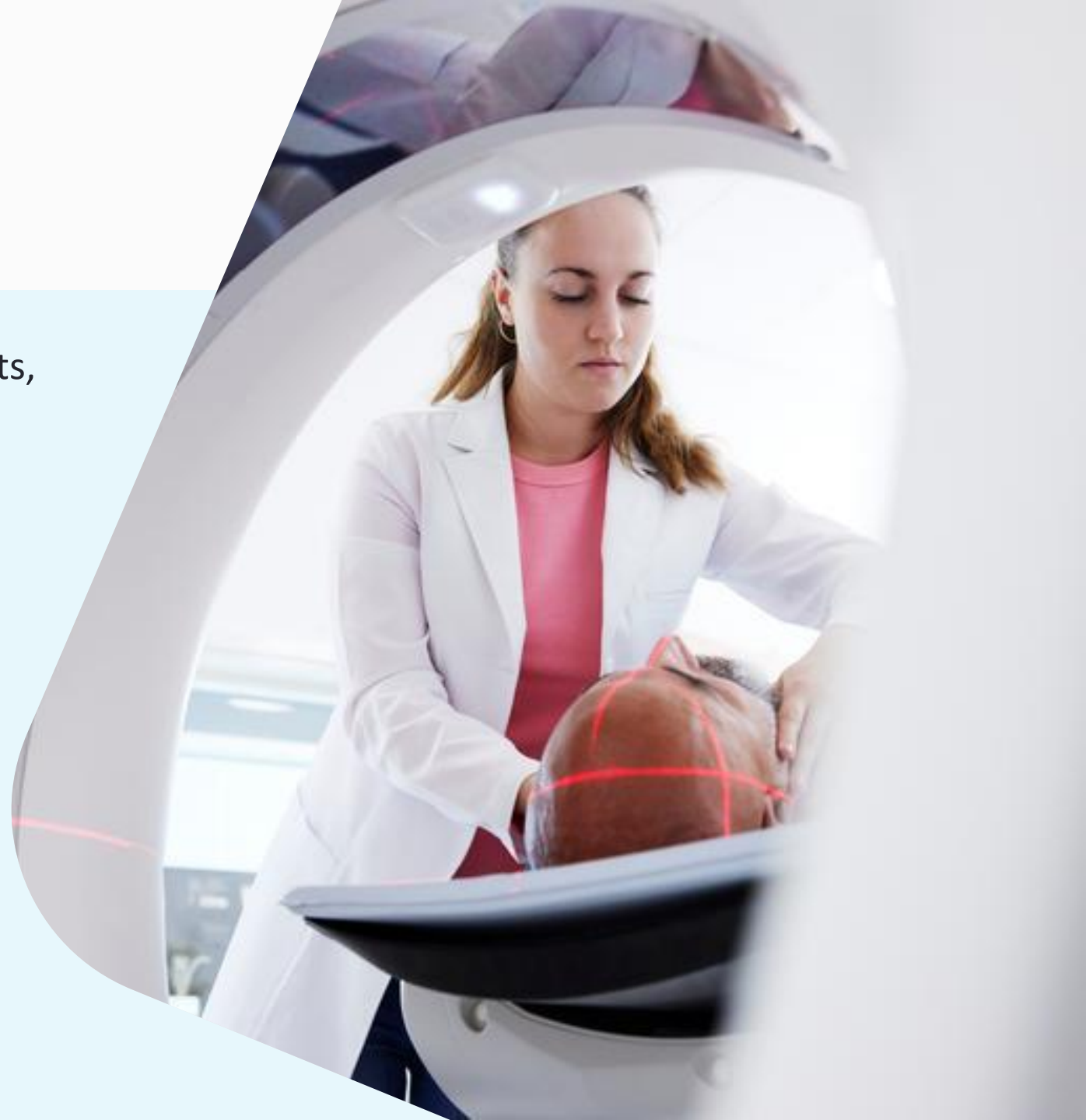
# Poll question

# Relationship between AA&DT and other forms of AI assessment

A voluntary AA&DT can help prepare for a conformity assessment under the EU AI Act

- After the transition period for the EU AI Act, any provider or deployer of high-risk AI systems in the EU market will be required to undergo a third-party conformity assessment

- This assessment may involve verifying that datasets and algorithms conform to harmonised state of the art standards

- AA&DT can be complementary to other forms of voluntary assessment, such as certification against ISO 42001 (AI management systems)



EN                                                                    OJ L, 12.7.2024

ANNEX VII

**Conformity based on an assessment of the quality management system and an assessment of the technical documentation**

4.3.    The technical documentation shall be examined by the notified body. Where relevant, and limited to what is necessary to fulfil its tasks, the notified body shall be granted full access to the training, validation, and testing data sets used, including, where appropriate and subject to security safeguards, through API or other relevant technical means and tools enabling remote access.

4.4.    In examining the technical documentation, the notified body may require that the provider supply further evidence or carry out further tests so as to enable a proper assessment of the conformity of the AI system with the requirements set out in Chapter III, Section 2. Where the notified body is not satisfied with the tests carried out by the provider, the notified body shall itself directly carry out adequate tests, as appropriate.

4.5.    Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Chapter III, Section 2, after all other reasonable means to verify conformity have been exhausted and have proven to be insufficient, and upon a reasoned request, the notified body shall also be granted access to the training and trained models of the AI system, including its relevant parameters. Such access shall be subject to existing Union law on the protection of intellectual property and trade secrets.

# Benefits of a voluntary AA&DT

A voluntary AA&DT demonstrates confidence in your AI systems

- The AA&DT deliverable confirms that:
  - Your models and datasets have been assessed by independent, third-party experts, using extensively validated methods based on ISO standards
  - The values of the performance metrics that you are calculating internally have been verified

- The Confirmation Letter can:
  - Supply confidence to your customers or to your investors
  - Supply confidence to your internal AI development teams in their processes
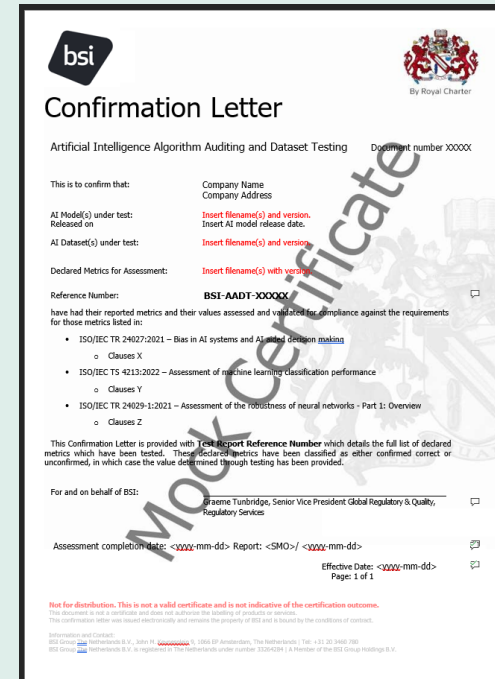
# Poll question

# Medical Imaging Use Case 1

**Background**: An Asia-based startup company, designing an AI system to segment and classify retinal pathologies

- Approaching investors for additional funding to position their system in the EU

- Datasets from Asian and EU populations

**Insight**: AA&DT verifies the performance of their AI system, including parity across populations

**Value**: Confirmation Letter can demonstrate confidence to investors and customers, and AA&DT can prepare for a conformity assessment under the EU AI Act



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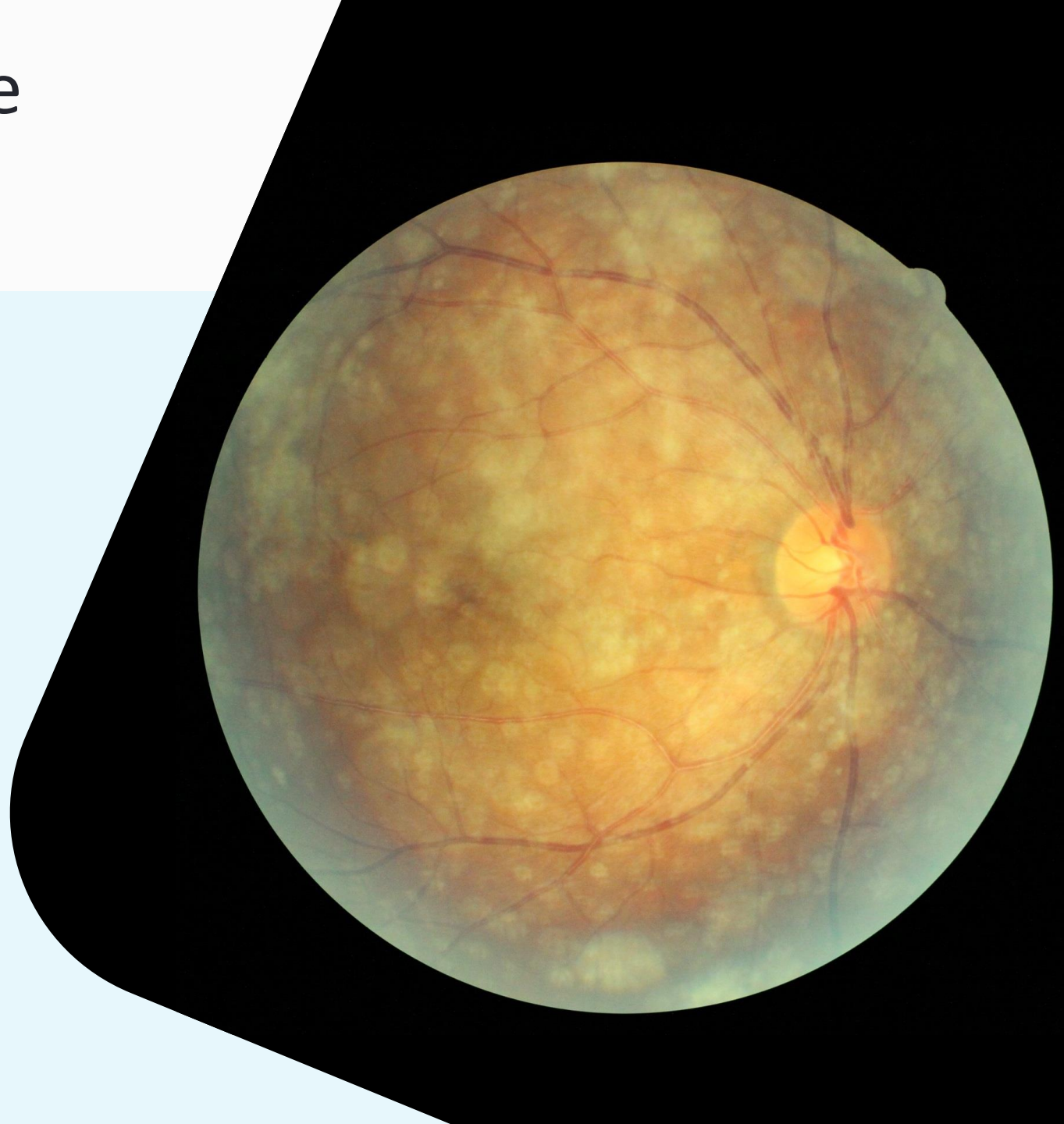
# Medical Imaging Use Case 2

**Background**: A US manufacturer of an AI system to detect forms of cardiac arrhythmia

- Expanding the range of supported implantable devices

- Concerned about performance with signal degradations e.g. gain, noise

**Insight**: AA&DT verifies the performance of their AI system, including parity across supported devices and robustness to perturbed input signals

**Value**: Confirmation Letter can demonstrate confidence in supported devices, and AA&DT
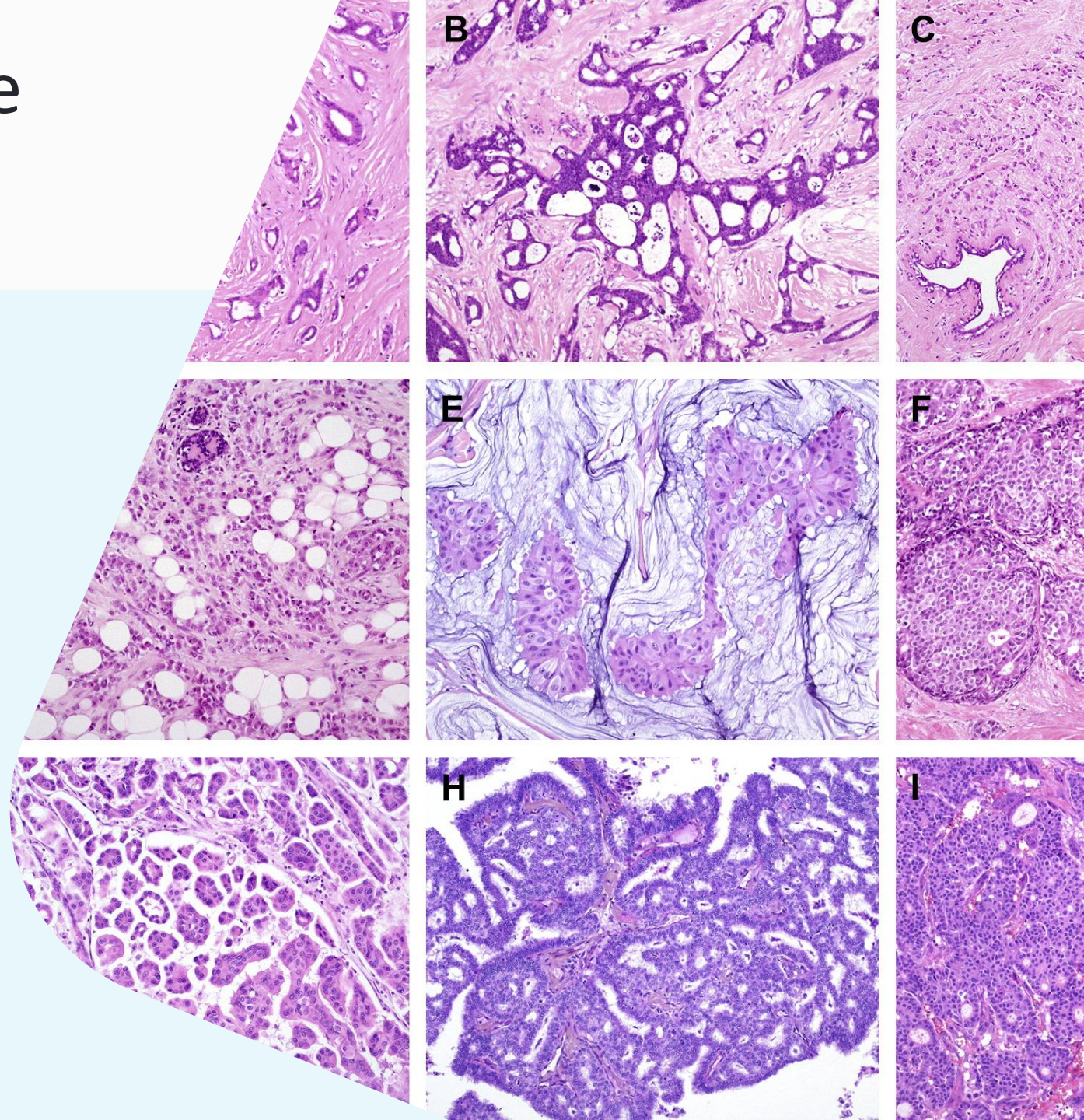can prepare for a conformity assessment
under the EU AI Act

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# Medical Imaging Use Case 3

**Background**: A manufacturer of an AI system to identify early signs of breast cancer from histopathology slides

- Introducing a new version of their AI system soon

- Regularly updating libraries/dependencies

**Insight**: AA&DT verifies the performance of their AI system across software versions during the change process

**Value**: AA&DT can be used periodically as part of an MLOps process to verify performance across versions

# Summary

**A voluntary AA&DT with BSI:**

- Involves sharing a copy of your datasets and models with BSI so that we can verify performance – including bias and robustness – using standards-based metrics

- Can help you prepare for a conformity assessment under the EU AI Act

- Can demonstrate confidence in your AI system to your customers, your investors, and your internal development teams

**bsi** Your partner in progress

Q&A

**bsi**

# Thank you for attending!