Safety Assurance FRamework for Machine Learning in the Healthcare Domain (SAFR)

Presented by:
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Assessing Methods and Tools to Improve Reporting, Increase Transparency, and Reduce Failures in Machine Learning Applications in Health Care

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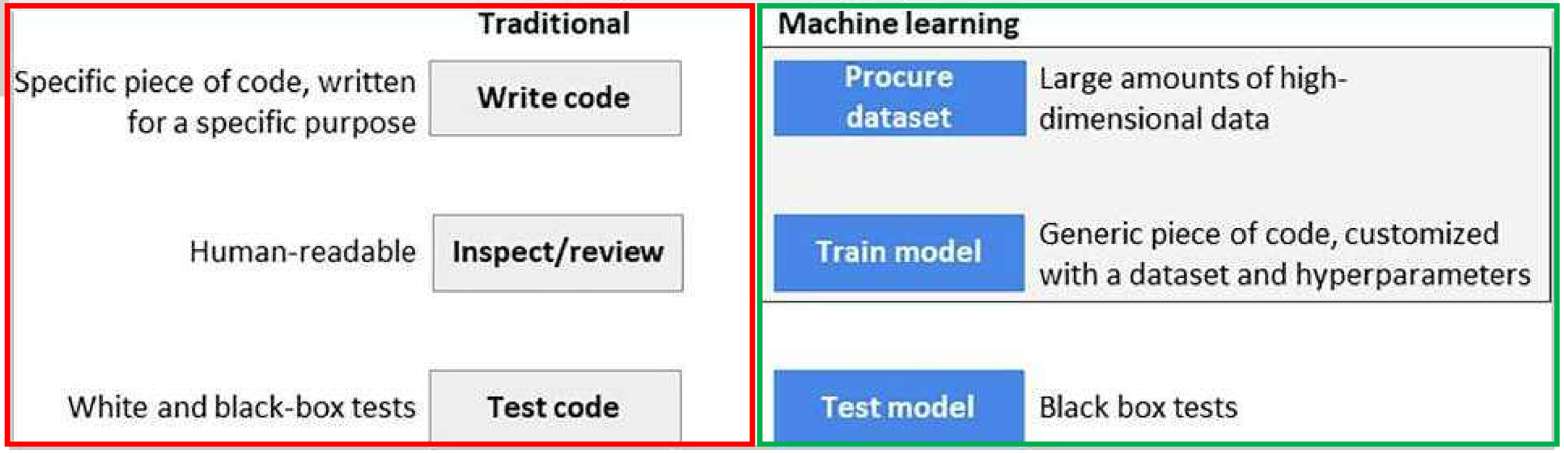
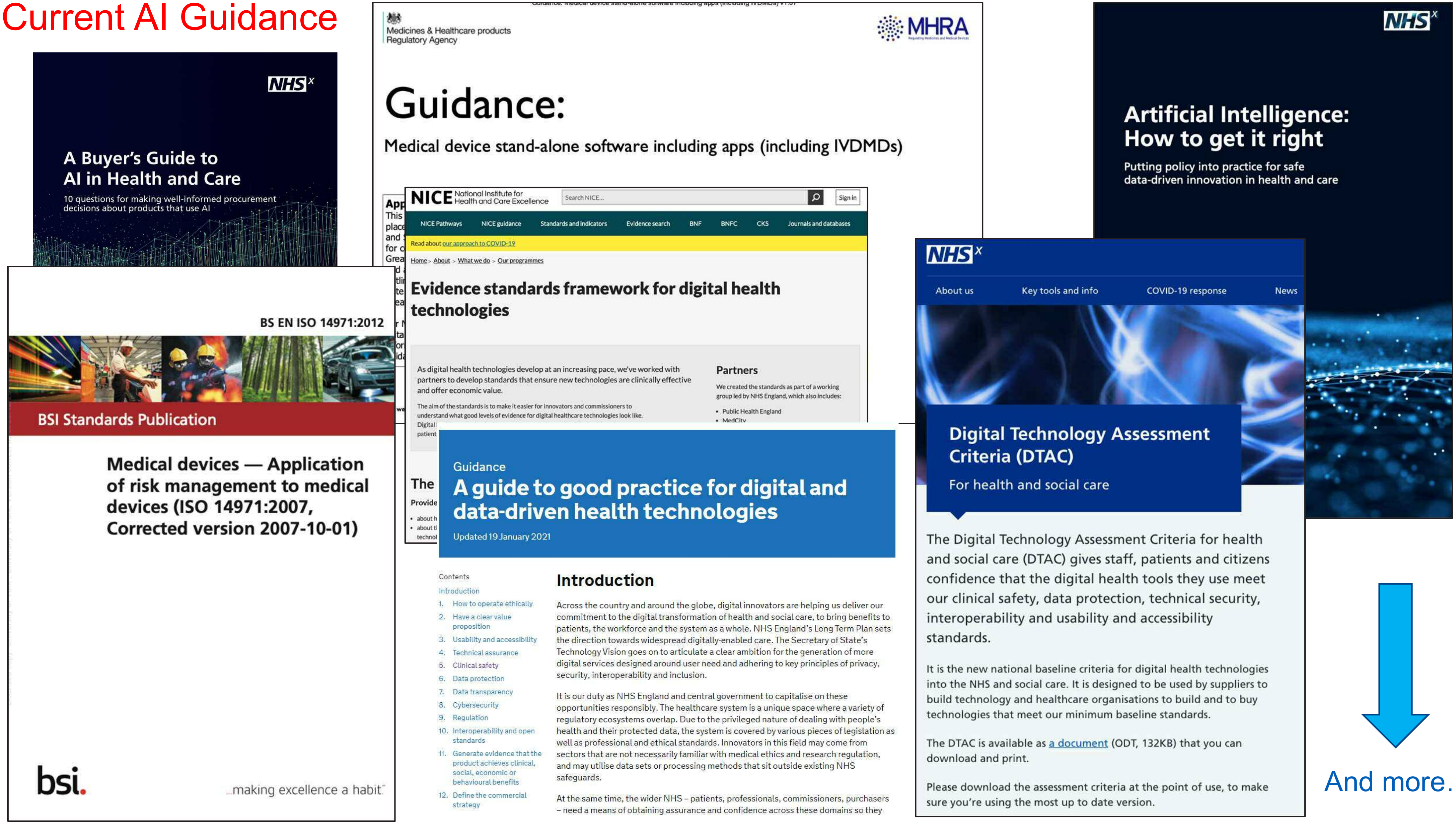
Artificial intelligence applications for health care have come a long way. Despite the remarkable progress, there are several examples of unfulfilled promises and outright failures. There is still a struggle to translate successful research into successful real-world applications. Machine learning (ML) products diverge from traditional software products in fundamental ways. Particularly, the main component of an ML solution is not a specific piece of code that is written for a specific purpose; rather, it is a generic piece of code, a model, customized by a training process driven by hyperparameters and a dataset. Datasets are usually large, and models are opaque. Therefore, datasets and models cannot be inspected in the same, direct way as traditional software products. Other methods are needed to detect failures in ML products. This report investigates recent advancements that promote auditing, supported by transparency, as a mechanism to detect potential failures in ML products for health care applications. It reviews practices that apply to the early stages of the ML lifecycle, when datasets and models are created; these stages are unique to ML products. Concretely, this report demonstrates how two recently proposed checklists, datasheets for datasets and model cards, can be adopted to increase the transparency of crucial stages of the ML lifecycle, using ChestX-ray8 and CheXNet as examples. The adoption of checklists to document the strengths, limitations, and applications of datasets and models in a structured format leads to increased transparency, allowing early detection of potential problems and opportunities for improvement.

Supplemental material is available for this article.

1. Define the problem to be solved.
2. Procure a dataset
3. Train the model
4. Test the product
5. Release the product
6. Monitor the behaviour of the product



Current AI Guidance



And more…

Assurance of Machine Learning for use in Autonomous Systems (AMLAS)

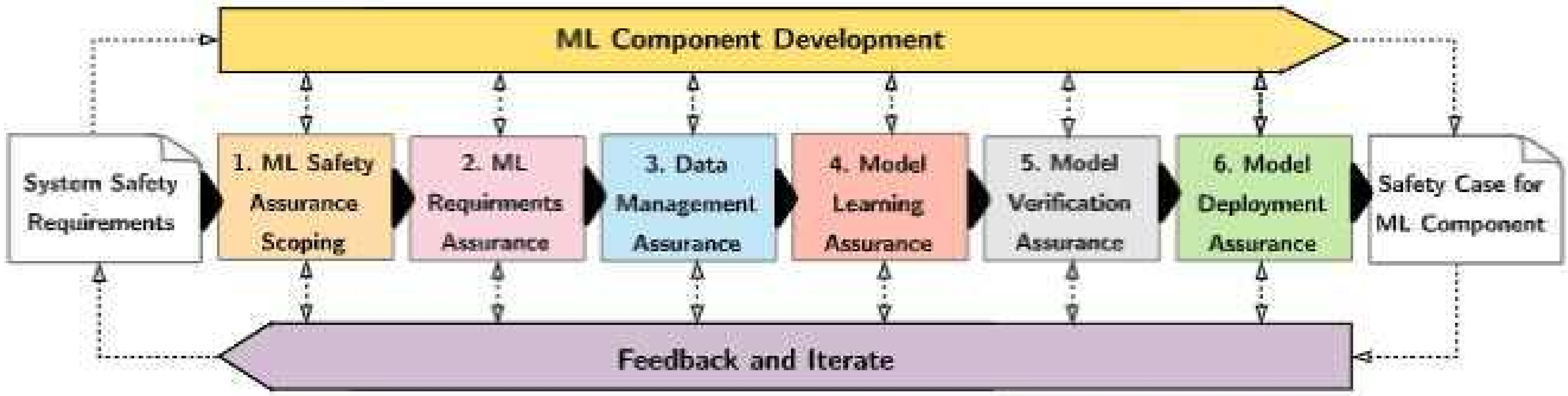
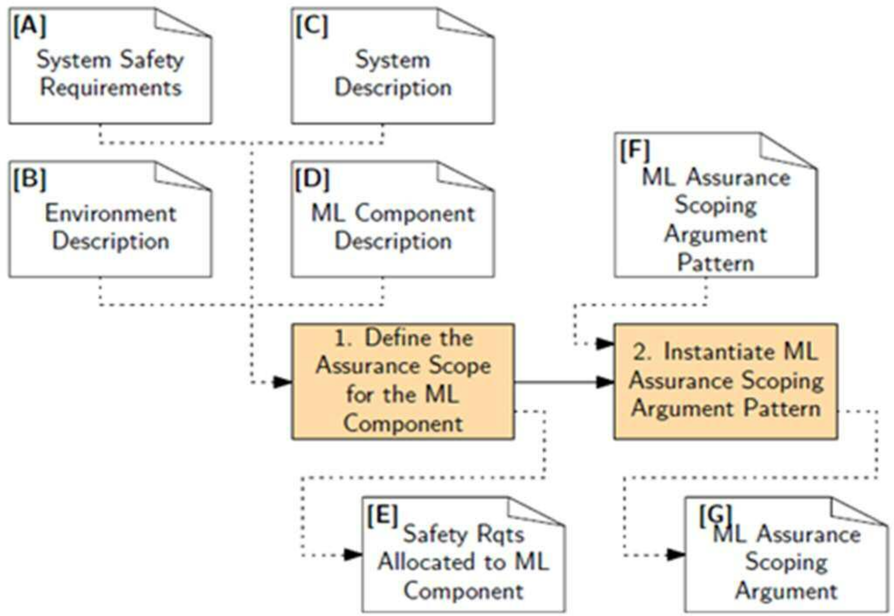


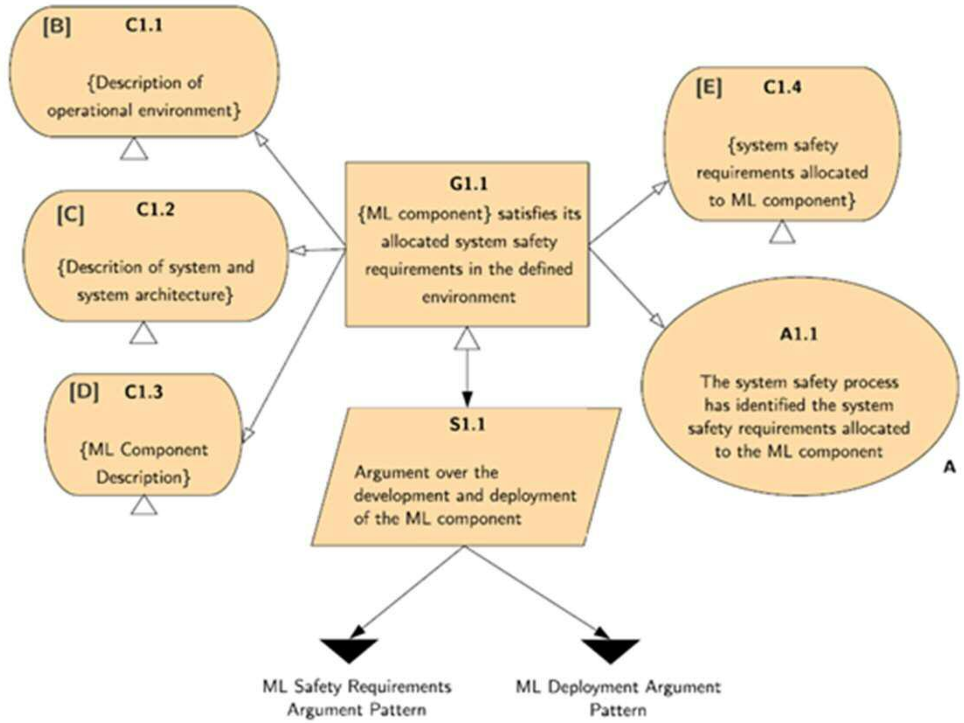
Figure 1: Overview of the AMLAS Process

Assurance of Machine Learning for use in Autonomous Systems (AMLAS)

Process



Argument Pattern



Assurance of Machine Learning for use in Autonomous Systems (AMLAS)

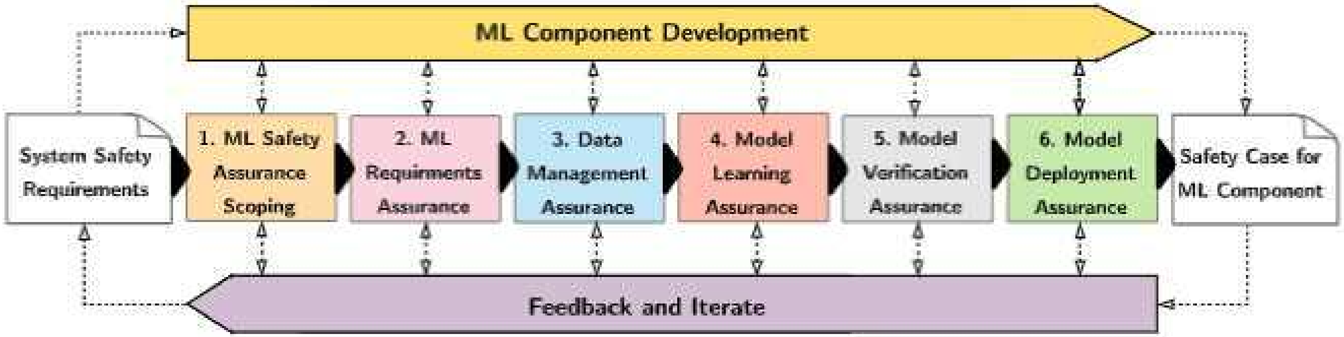
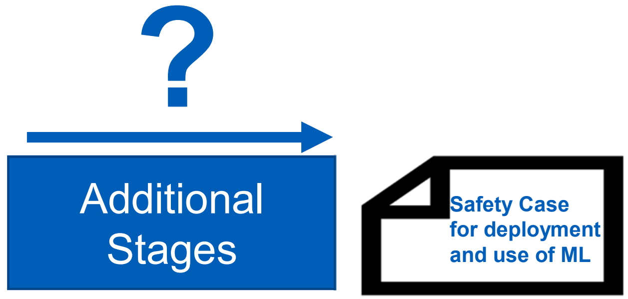
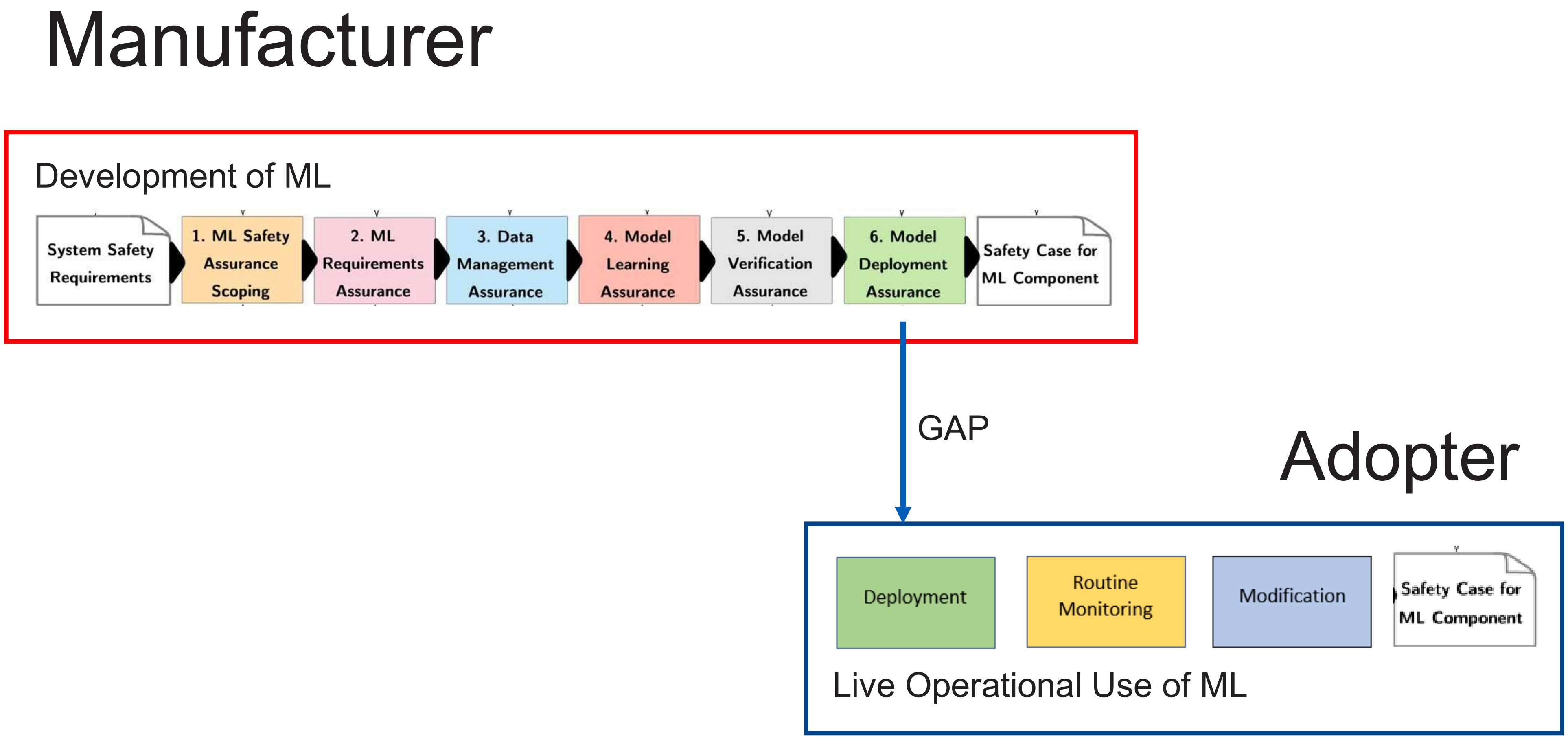


Figure 1: Overview of the AMLAS Process



- Summary of findings:
- Development of healthcare specific guidance for AMLAS
- Develop additional stages for deploying healthcare organisations (Adopters)



Manufacturer
Development of ML
System Safety Requirements
1. ML Safety Assurance Scoping
2. ML Requirements Assurance
3. Data Management Assurance
4. Model Learning Assurance
5. Model Verification Assurance
6. Model Deployment Assurance
Safety Case for ML Component
GAP
Adopter
Deployment
Routine Monitoring
Modification
Safety Case for ML Component
Live Operational Use of ML

Risk-Confidence-Conformance Approach

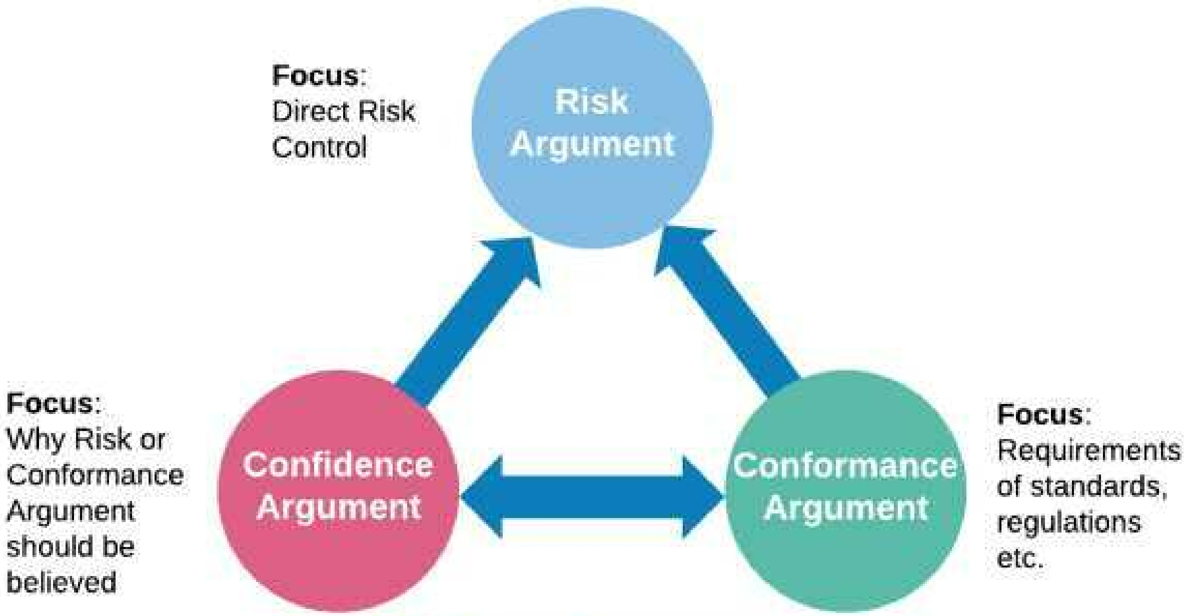
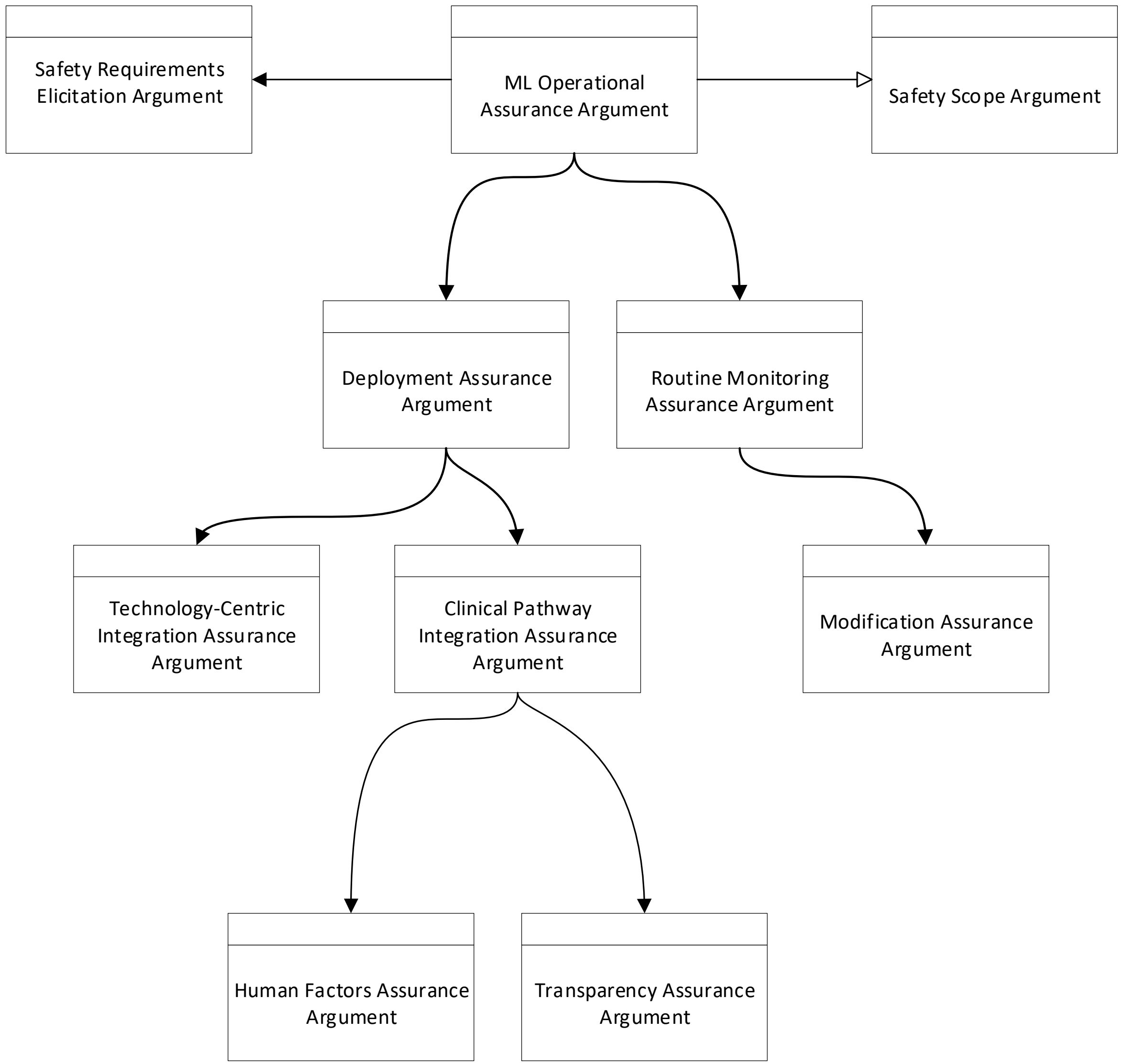
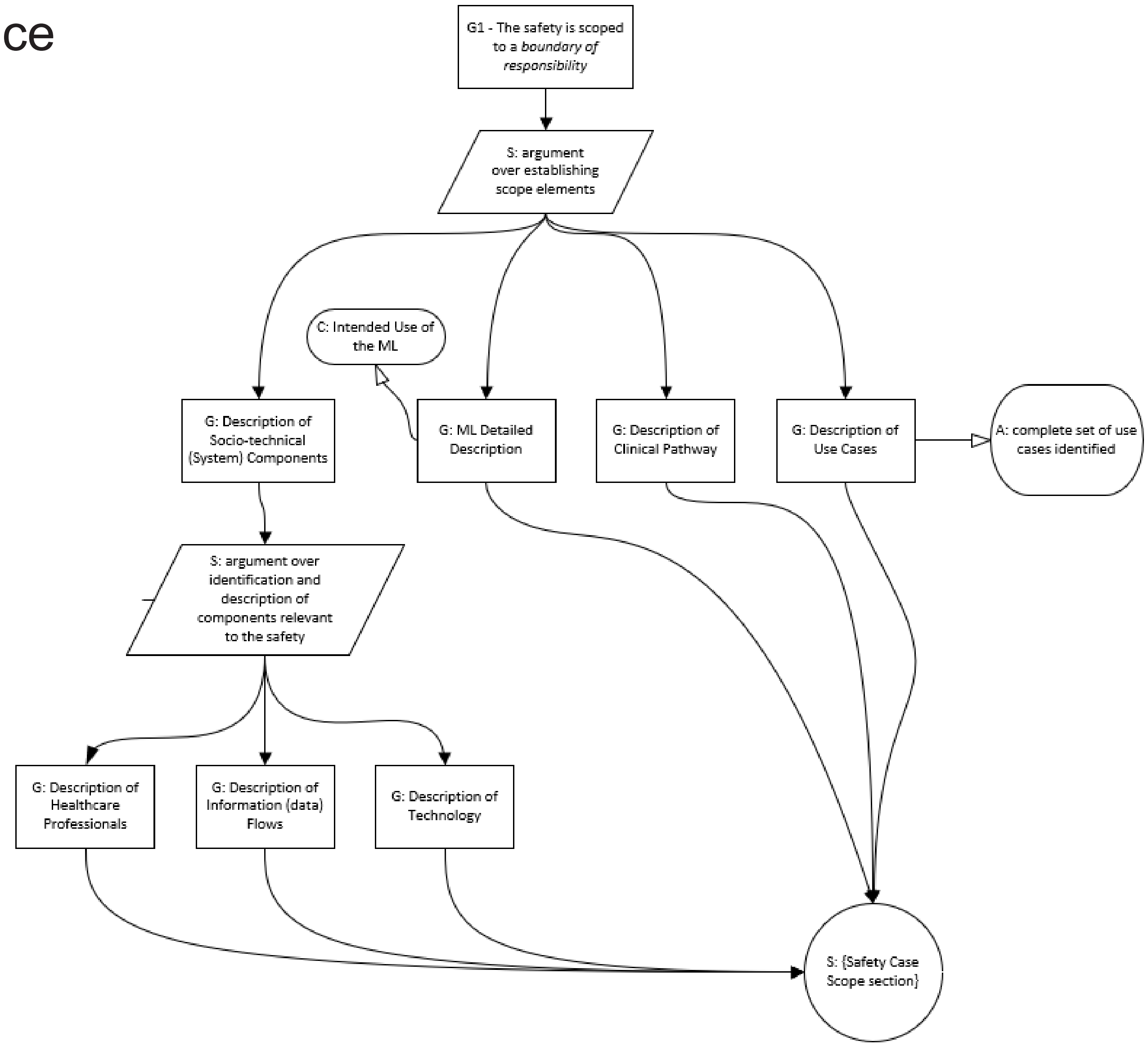


Figure 2:5-1 - Types of assurance case argument

Proposed Assurance Argument Overview



Safety Scope Assurance Argument Example



Google – Diabetic Retinopathy

- Real-world images lower quality than training set
- Technical hardware limitations
- Workflow variance

Real-time diabetic retinopathy screening by deep learning in a multisite national screening programme: a prospective interventional cohort study

Paisan Ruamviboonsuk, Richa Tiwari, Rory Sayres, Variya Nganthavee, Kornwipa Hemarat, Apinpat Kongprayoon, Rajiv Raman, Brian Levinstein, Yun Liu, Mike Schaekermann, Roy Lee, Sunny Virmani, Kasumi Widner, John Chambers, Fred Hersch, Lily Peng, Dale R Webster

Summary

Background Diabetic retinopathy is a leading cause of preventable blindness, especially in low-income and middle-income countries (LMICs). Deep-learning systems have the potential to enhance diabetic retinopathy screenings in these settings, yet prospective studies assessing their usability and performance are scarce.

Methods We did a prospective interventional cohort study to evaluate the real-world performance and feasibility of deploying a deep-learning system into the health-care system of Thailand. Patients with diabetes and listed on the national diabetes registry, aged 18 years or older, able to have their fundus photograph taken for at least one eye, and due for screening as per the Thai Ministry of Public Health guidelines were eligible for inclusion. Eligible patients were screened with the deep-learning system at nine primary care sites under Thailand's national diabetic retinopathy screening programme. Patients with a previous diagnosis of diabetic macular oedema, severe non-proliferative diabetic retinopathy, or proliferative diabetic retinopathy; previous laser treatment of the retina or retinal surgery; other non-diabetic retinopathy eye disease requiring referral to an ophthalmologist; or inability to have fundus photograph taken of both eyes for any reason were excluded. Deep-learning system-based interpretations of patient fundus images and referral recommendations were provided in real time. As a safety mechanism, regional retina specialists over-read each image. Performance of the deep-learning system (accuracy, sensitivity, specificity, positive predictive value [PPV], and negative predictive value [NPV]) were measured against an adjudicated reference standard, provided by fellowship-trained retina specialists. This study is registered with the Thai national clinical trials registry, TCRT20190902002.

MHRA Work Packages

WP 4 Post market

1. Implement a robust post market surveillance system that produces a strong and clear safety signal, allowing for quicker and th
SaMD
2. Utilise real world evidence to provide further
intended, maintains performance, and contin
to safety
3. Articulate clear change management require

WP 10 Project Glass Box (AI Interpretability)

1. Articulate how opacity in AIaMD can translate into safety or effectiveness issues
2. Develop frameworks regarding interpretability of AIaMD to ensure that AI models are sufficiently transparent to be robust and testable or are otherwise properly validated
3. Develop frameworks regarding interpretability of AIaMD to ensure that interpretability's relationship to usability is made plain and emphasised in relation to safety and effectiveness

WP 9 Project AI RIG (AI Rigour)

1. Utilise existing and broadly accepted frameworks to ensure AI as a medical device (AIaMD) placed on the market provides robust assurance that it is safe and effective
2. Develop supplementary frameworks to ensure AIaMD placed on the market provides robust assurance with respect to safety and effectiveness, with a special emphasis on ensuring that AIaMD is fit for purpose for all populations in which it is intended to be used
3. Develop technical methods to test AIaMD to ensure the device is safe and effective

MHRA, *Software and AI as a Medical Device Change Programme*. 2021

CQC – Healthcare Services Regulator

Using machine learning in diagnostic services

A report with recommendations from CQC's regulatory sandbox

- Audit Services not ML
- Recognised need to update their approach

CQC, *Using machine learning in diagnostics services*. 2020

Questions?