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See beyond a single case.

EU Artificial Intelligence Act & Implementation at contextflow

presented by

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Agenda

- Introduction to contextflow and AI/ML-based MDSW

- EU Artificial Intelligence Act
  - Purpose & Scope
  - Applicability
  - Classification of High Risk AI
  - Requirements for High Risk AI

- Relation to MDR (EU) 2017/745

- Best Practices at contextflow

- Status Quo

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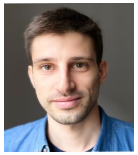

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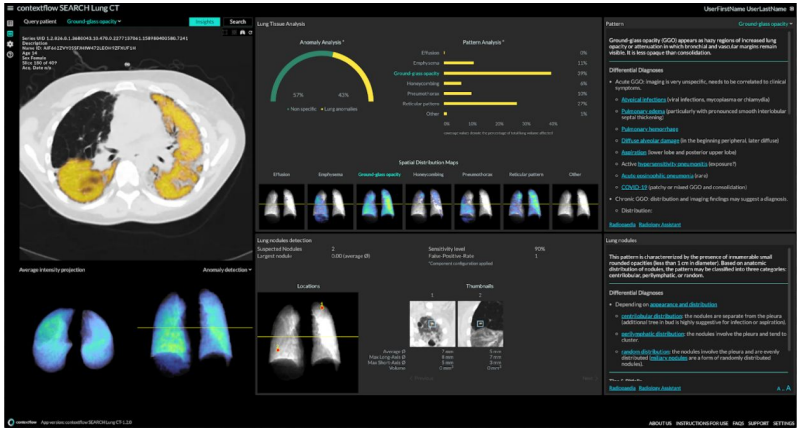
AI & Medical Image Analysis Experts with 40+ years' experience & 250+ peer reviewed publications

Domain-specific sales and business development expertise through scaling radiology speech recognition software from 0 to 30m€ annual revenue in 8 years

Intended Use

contextflow SEARCH Lung CT provides radiologists with complementary information to identify and interpret lung specific image patterns in computed tomography (CT) scans.
For this aim, the system offers the following functionalities:

- **Quantitative Image Analysis:** automated detection, quantification and visualization of lung abnormalities and specific image patterns
- **Qualitative Analysis:** based on the selected image regions; both visual image search from a knowledge base of retrospective cases labeled by experts and pattern classification are presented
- **Reference Informationen for image patterns:** Links to literature, articles or guidelines, tips and pitfalls, and possible differential diagnosis



EU Artificial Intelligence Act

Quality Criteria for MDSW

Core requirements for medical device software development

- EN ISO 13485 Medical devices - quality management systems
- IEC 62304 Medical device software - Software life cycle processes
- IEC 82304-1 Health software - Part 1 general requirements for product safety
- EN ISO 14971 Medical devices - Application of risk management to medical devices
- IEC 62366-1 Medical devices - Part 1 Application of usability engineering to medical devices

Data, data, data...

- **EU AIA (Artificial Intelligence Act)**

Regulation Architecture: Articles

TITEL	CHAPTER	ARTICLE
TITLE I: GENERAL PROVISIONS	N/A	Article 1-4
TITLE II: PROHIBITED ARTIFICIAL INTELLIGENCE PRACTICES	N/A	Article 5
TITLE III HIGH-RISK AI SYSTEMS	Chapter 1 Classification Of AI Systems As High-risk	Article 6-7
	Chapter 2 Requirements For High-risk AI Systems	Article 8-15
	Chapter 3 Obligations Of Providers And Users Of High-risk AI Systems And Other Parties	Article 16-29
	Chapter 4 Notifiying Authorities And Notified Bodies	Article 29-39
	Chapter 5 Standards, Conformity Assessment, Certificates, Registration	Article 39-51
TITLE IV TRANSPARENCY OBLIGATIONS FOR CERTAIN AI SYSTEMS	N/A	Article 52
TITLE V MEASURES IN SUPPORT OF INNOVATION	N/A	Article 53-55

Regulation Architecture: Articles

TITEL	CHAPTER	ARTICLE
TITLE VI GOVERNANCE	Chapter 1 European Artificial Intelligence Board	Article 56-58
	Chapter 2 National Competent Authorities	Article 59
TITLE VII EU DATABASE FOR STAND-ALONE HIGH-RISK AI SYSTEMS	N/A	Article 60
TITLE VIII POST-MARKET MONITORING, INFORMATION SHARING, MARKET SURVEILLANCE	Chapter 1 Post-market Monitoring	Article 61
	Chapter 2 Sharing Of Information On Incidents And Malfunctioning	Article 62
	Chapter 3 Enforcement	Article 63-68
TITLE IX CODES OF CONDUCT	N/A	Article 69
TITLE X CONFIDENTIALITY AND PENALTIES	N/A	Article 71-72
TITLE XI DELEGATION OF POWER AND COMMITTEE PROCEDURE	N/A	Article 73-74
TITLE XII FINAL PROVISIONS	N/A	Article 75-85

Regulation Architecture: Annexes

ANNEX	DESCRIPTION
ANNEX I	Artificial Intelligence Techniques And Approaches
ANNEX II	List Of Union Harmonisation Legislation
ANNEX III	High-risk AI Systems Referred To In Article 6(2)
ANNEX IV	Technical Documentation Referred To In Article 11(1)
ANNEX V	EU Declaration Of Conformity
ANNEX VI	Conformity Assessment Procedure Based On Internal Control
ANNEX VII	Conformity Based On Assessment Of Quality Management System And Assessment Of Technical Documentation
ANNEX VIII	Information To Be Submitted Upon The Registration Of Highrisk AI Systems In Accordance With Article 51
ANNEX IX	Union Legislation On Large-scale It Systems In The Area Of Freedom, Security And Justice

General Information: Purpose & Scope

Purpose of regulation

- To ensure the protection of fundamental rights and user safety
- To enhance trust in the development and uptake of AI

Scope of application

- To both public and private actors inside and outside the EU
  - As long as the AI system is placed on the Union market **or**
  - Its use affects people located in the EU

General Information: Definition of AI system acc. AI Act

‘artificial intelligence system’ (AI system) means software

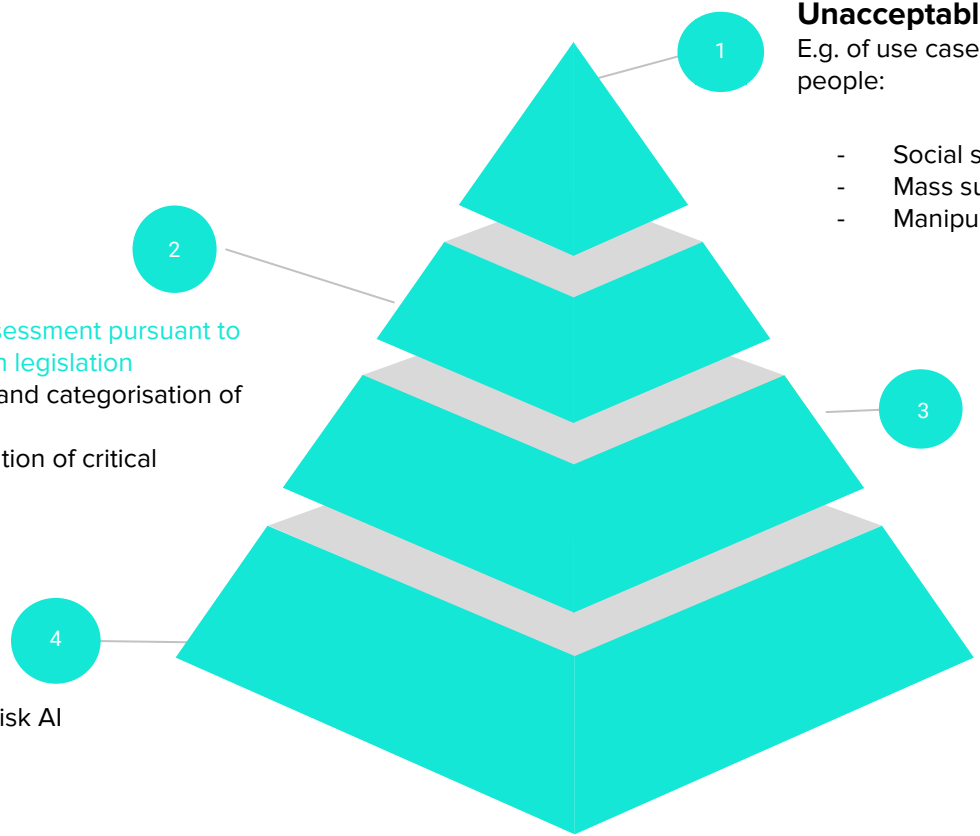
- that is developed with one or more of the techniques and approaches listed in Annex I and
- can, for a given set of human-defined objectives,
  - generate outputs such as
    - content,
    - predictions,
    - recommendations, or
    - decisions influencing the environments they interact with

General Information: AI Techniques

Types of AI techniques covered by the AI Act Article 3/Annex I

- Machine learning approaches including:
  - supervised, unsupervised and reinforcement learning
  - using a wide variety of methods including deep learning
- Logic- and knowledge-based approaches, including:
  - knowledge representation
  - inductive (logic) programming
  - knowledge bases
  - inference and deductive engines
  - (symbolic) reasoning and expert systems
- Statistical approaches, Bayesian estimation, search and optimization methods

4 Risk Categories



Unacceptable Risk
E.g. of use cases related to safety, livelihoods and rights of people:

- Social scoring
- Mass surveillance
- Manipulation of human behaviour causing harm

High Risk
E.g. of use cases:

- 3rd party conformity assessment pursuant to the Union harmonisation legislation
- Biometric identification and categorisation of natural persons
- Management and operation of critical infrastructure

Limited Risk
E.g. of use cases:

- Chatbots

Minimal Risk
E.g. of use cases:

- Class I acc. MDR low risk AI applications

AI Act Applicability & Classification

Article 3/Annex I

E.g. Deep learning algorithm, knowledge bases, statistical approaches

Article 5

E.g. AI system that causes physical or psychological harm

Annex II

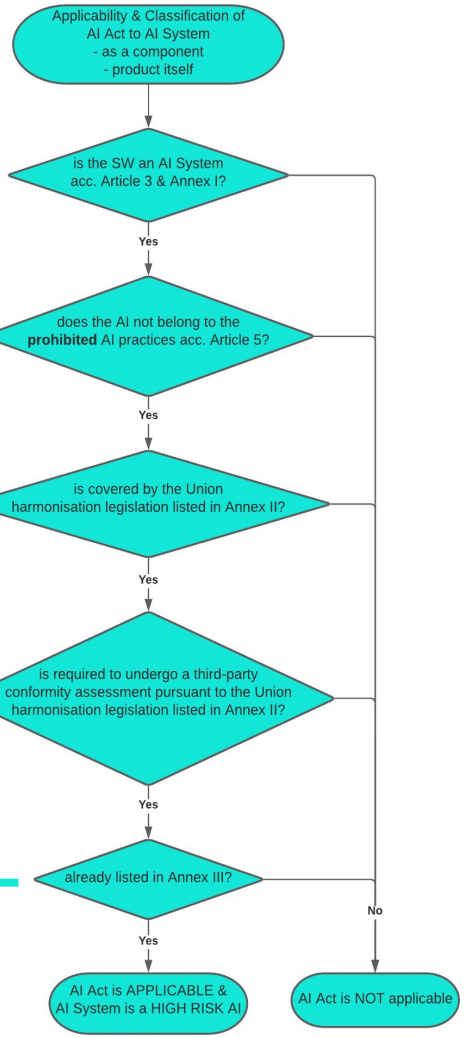
E.g. Regulation (EU) 2017/745 - MDR

E.g. Regulation (EU) 2017/746 - IVDR

Annex III

E.g. Biometric identification and categorisation of natural persons

E.g. Education and vocational training



High Risk AI: Mandatory Requirements

Article & Annex	Description
Article 9	Risk management system
Article 10	Data and data governance
Article 11 & Annex IV	Technical documentation
Article 12	Record-keeping
Article 13	Transparency and provision of information to users
Article 14	Human oversight
Article 15	Accuracy, robustness and cybersecurity
Article 17	Quality management system
Article 49	CE marking of conformity
Article 51	Registration

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Article 17	**Quality management system**
Article 49	CE marking of conformity
Article 51	Registration

Penalties - Administrative Fines

Non-compliance with	Penalties [EUR] for non-compliance
The prohibition of the artificial intelligence practices referred to in **Article 5 (Prohibited AI Practices)** The requirements laid down in **Article 10 (Data & Data Governance)**	**Individual**: up to **30 M** **Company**: up to **30 M** or **6 % of its total worldwide annual turnover** for the preceding financial year, whichever is higher
Any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10	Individual: up to 20 M Company: up to 20 M or 4 % of its total worldwide annual turnover for the preceding financial year, whichever is higher
Supply of incorrect, incomplete or misleading information to notified bodies and national competent authorities	Individual: up to 10 M Company: up to 10 M or 2 % of its total worldwide annual turnover for the preceding financial year, whichever is higher

Relation to MDR (EU) 2017/745

High Risk AI: Mandatory Requirements

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AI Act QMS Req. Comparison with MDR

AI Act Article 17	MDR (EU) 2017/745 Article 10(9)
1. (a) a strategy for regulatory compliance	(a) …a strategy for regulatory compliance
1. (b) techniques, procedures for the design, design control and design verification	(g) …product realisation
1. (c) techniques, procedures for the development, quality control and quality assurance	…QMS in general
1. (d) examination, test and validation procedures to be carried out before, during and after the development	…QMS in general + (f) …clinical evaluation
1. (e) technical specifications, including standards, to be applied	(b) …GSPR
1. (f) systems and procedures for data management (e.g. data collection, data analysis, data labelling, data storage, data retention)	…QMS in general
1. (g) the risk management system	(e) …risk management

AI Act QMS Req. Comparison with MDR

AI Act Article 17	MDR (EU) 2017/745 Article 10(9)
1. (h) the post-market monitoring system	(i) …PMS
1. (i) reporting of serious incidents	(k) …reporting serious incidents
1. (j) communication with national competent authorities, NBs	(j) …reporting serious incidents
1. (k) systems & procedures for record	…QMS in general
1. (l) resource management	(g) …resource management
1. (m) management responsibility	(c) …management responsibility

High Risk AI: Mandatory Requirements

Article & Annex	Description
Article 9	Risk management system
Article 10	Data and data governance
Article 11 & Annex IV	**Technical documentation**
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AI Act Technical Documentation Req. Comparison with MDR

AI Act Annex IV	MDR (EU) 2017/745
1. (a) - (g) A general description of the AI system: Instructions for Use	Annex I: GSPRs; Chapter III
2. (a) - (g) A detailed description of the elements of the AI system and of the process for its development	Article 10: General obligations of manufacturers; (4) *...draw up technical documentation* & (9) *...establish QMS*
3. Detailed information about the monitoring, functioning and control of the AI system	Article 83: Post-market surveillance system of the manufacturer
4. A detailed description of the risk management system ➔ Article 9	Annex I (GSPRs); Chapter I
5. A description of any change made to the system through its lifecycle	Annex IX: Conformity Assessment Based On A Quality Management System And On Assessment Of Technical Documentation; Chapter 2
6. A list of the harmonised standards applied	Article 8: Use of harmonised standards
7. A copy of the EU declaration of conformity	Article 10: General obligations of manufacturers; (6)
8. Post-market monitoring (PMM) plan ➔ Article 61(3)	Article 83: Post-market surveillance system of the manufacturer

Best Practices at contextflow

High Risk AI: Mandatory Requirements

Article & Annex	Description
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Best Practices at contextflow

Article 10 (2.) AI Act

Data & Data Governance
(a) relevant design choice (d) data outcome (g) data gaps identification
(b) data collection (e) data availability, quantity & suitability of the data sets (f) data biases examination
(c) data preparation processing operations

Processes in QMS	Requirements
PD Machine Learning	defines how AI architecture is built ● simpler model types
PD Data Procurement	defines how data sets to be used for ML, test data sets & validation data sets are identified collectected and stored ● amount of data ● representability of data ➜ avoid bias
PD Data Annotation	defines how data sets are annotated (labelled) ● skills for annotators ● accuracy of annotations

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Article 10 (5.) AI Act

Data & Data Governance	Processes in QMS	Requirements
pseudonymisation, anonymisation, encryption	PD Data Anonymization & Access	defines how to anonymize, encrypt and manage access to data

High Risk AI: Mandatory Requirements

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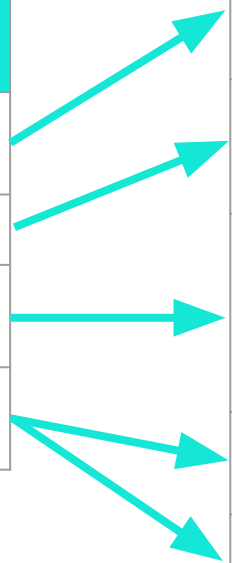
Best Practices at contextflow

Article 15 AI Act

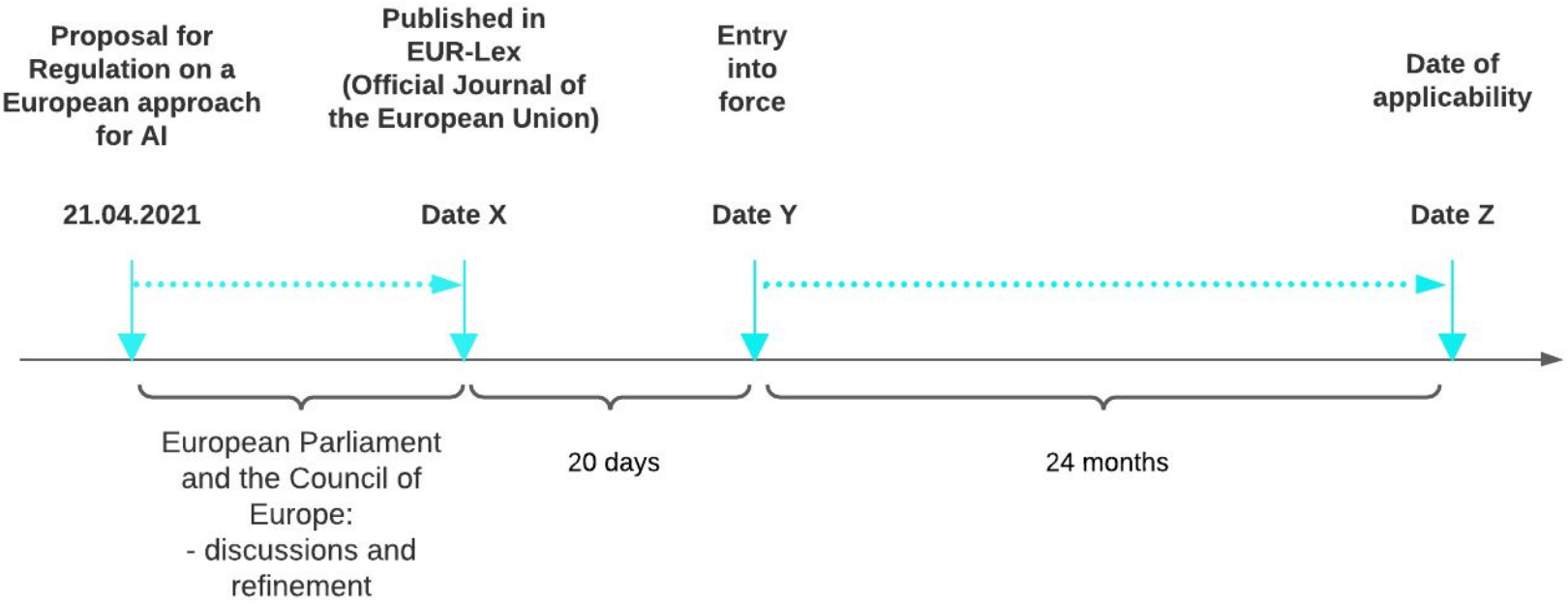
Accuracy, Robustness & and Cybersecurity
1. Consistent performance throughout their lifecycle
2. Accuracy metrics in IFU
3. Robustness: backup, fail-safe plans
4. Unauthorized access, cybersecurity risks & vulnerabilities



Processes in QMS	Requirements
PD Operational Review	defines what parameters to consider while performing Information System Activity Review - e.g. audit logs review: logins, file accesses
PD Market Clearance	defines how to perform market clearance for medical devices and which documents to be created - e.g. metrics for predicted vs standard clinical routine
PD Contingency Plan	establishes procedures to enable continuation of critical business processes for protection of data defines how to periodically test and revise contingency plans
PD Access Control Management	implements policies and procedures that protect the Data from unauthorized access
PD Cybersecurity Risk Management	manages the cybersecurity risks throughout the system - e.g. vulnerability scoring

Status Quo

Date of Application?



Take-home Message

Manufacturer of Class IIa and above MDSW acc. MDR

- Class I: NOT a high risk AI system ➔ AI Act is NOT applicable to Class I acc. MDR
- MDR certified ➔ No major changes in terms of AI implementation, in case of already existing GMLP in the QMS

Open Points

- Regulation of adaptive AI
- More clarification is required for AI regulatory sandboxes: for development, testing & validation
    - E.g. eligibility conditions

Thank you for your attention!

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See beyond a single case.

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