

# Intersection between **Clinical Evaluation,** Tech Companies & Regulatory

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digital health architects



	Tech Company		Regulatory	Clinical Evaluation
Task	Claim	Build AI	Deklare	Proove

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Theme	Business Strategy	Data Availability	Intended Use	Study Design

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When				
Why				
What				
Where				
Who				

# AI in Context as SaMD

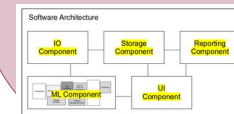
Idea

# AI in Context as SaMD

Tech Company

Idea

SW  
Development



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# Regulatory Domains

- Data Privacy → GDPR, HIPAA, other, none
- Health Risk → MDD / MDR, FDA, other, none
- Health Benefit → EBM / Clinical Practice Guidelines, none

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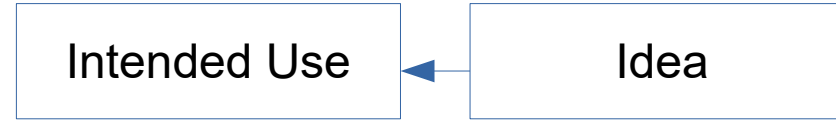
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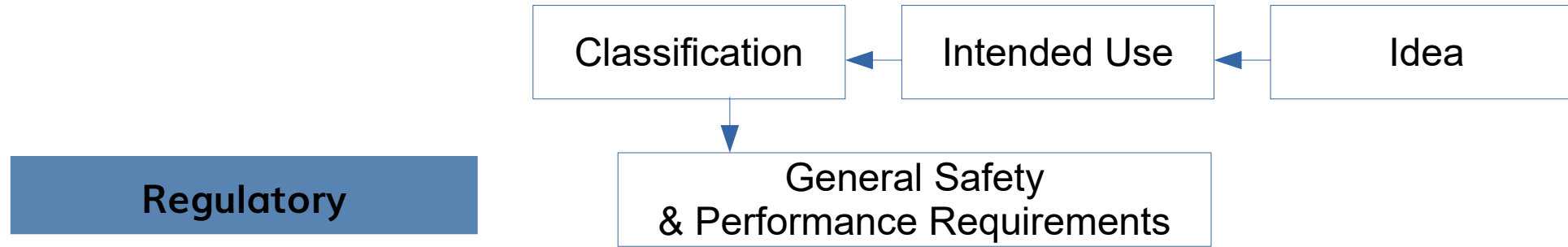
Regulatory

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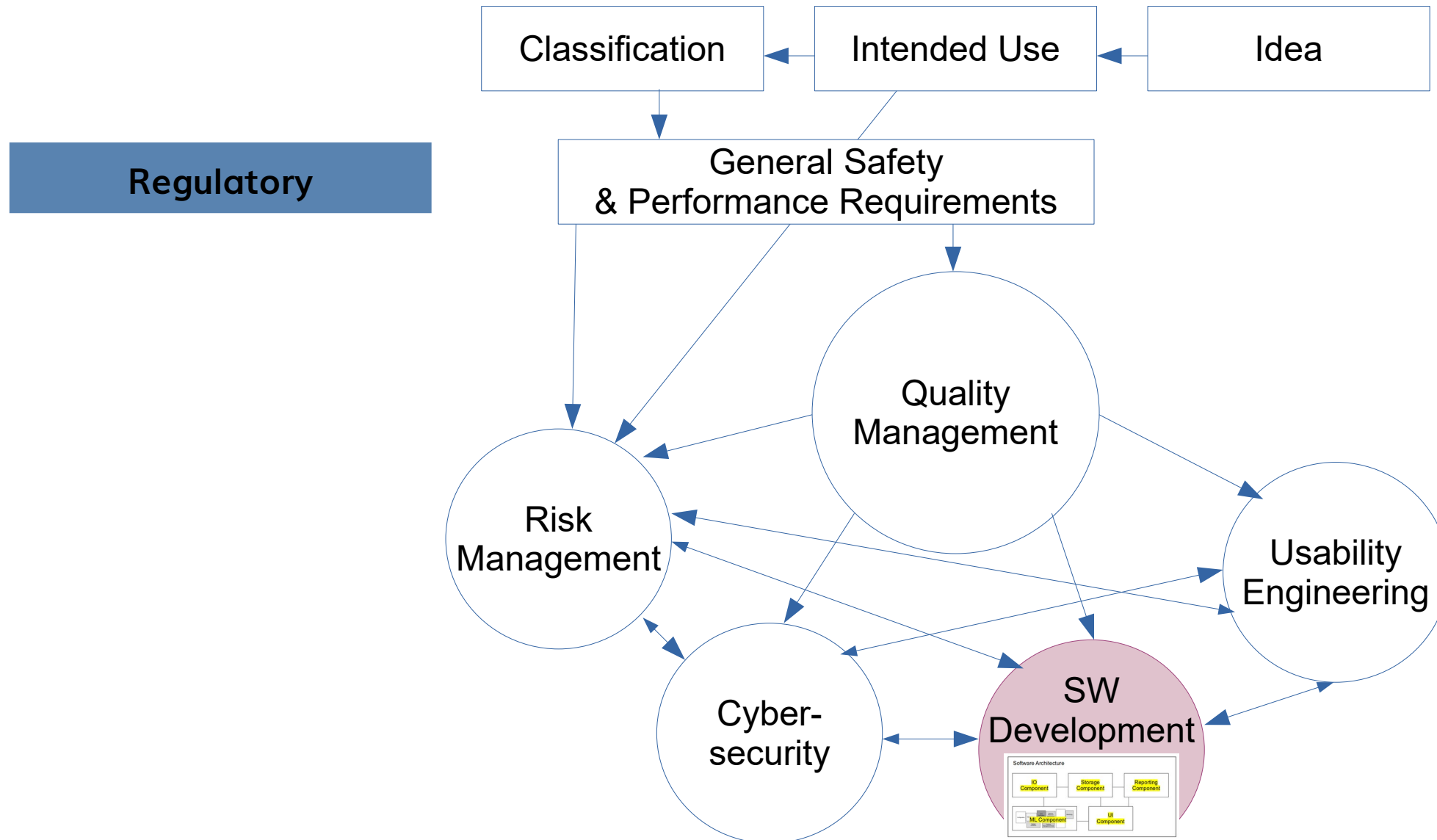


**Regulatory**

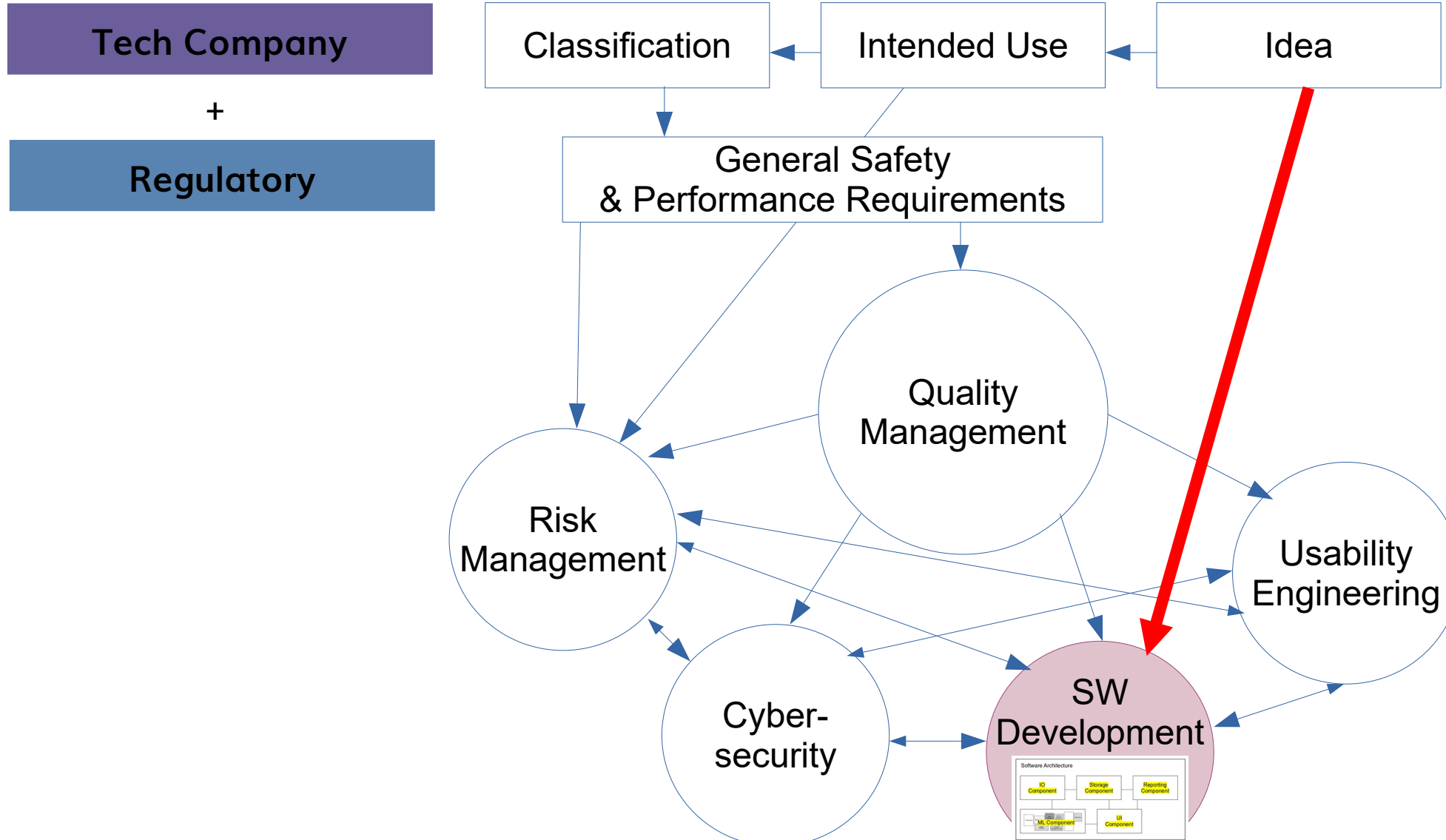
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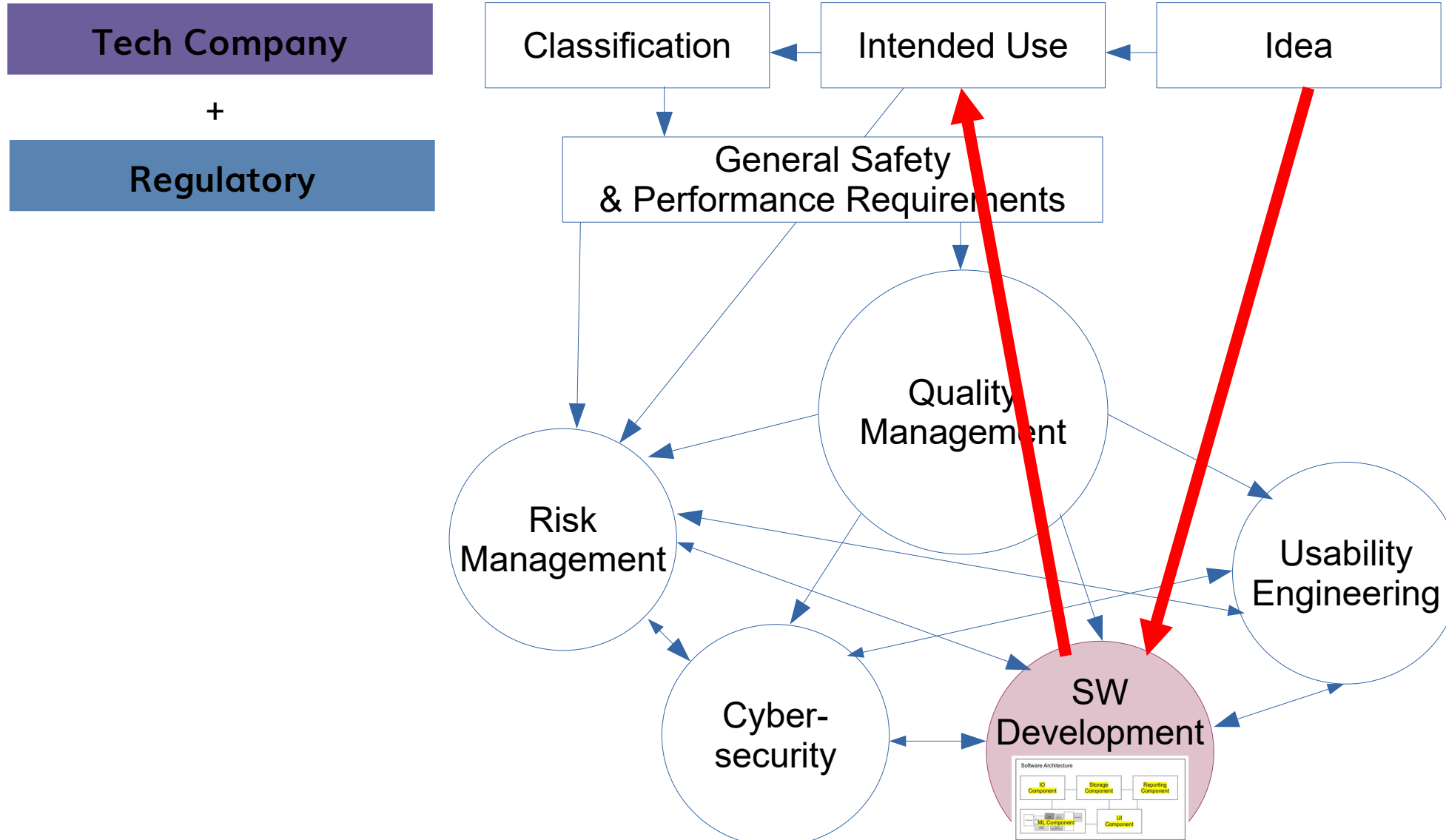
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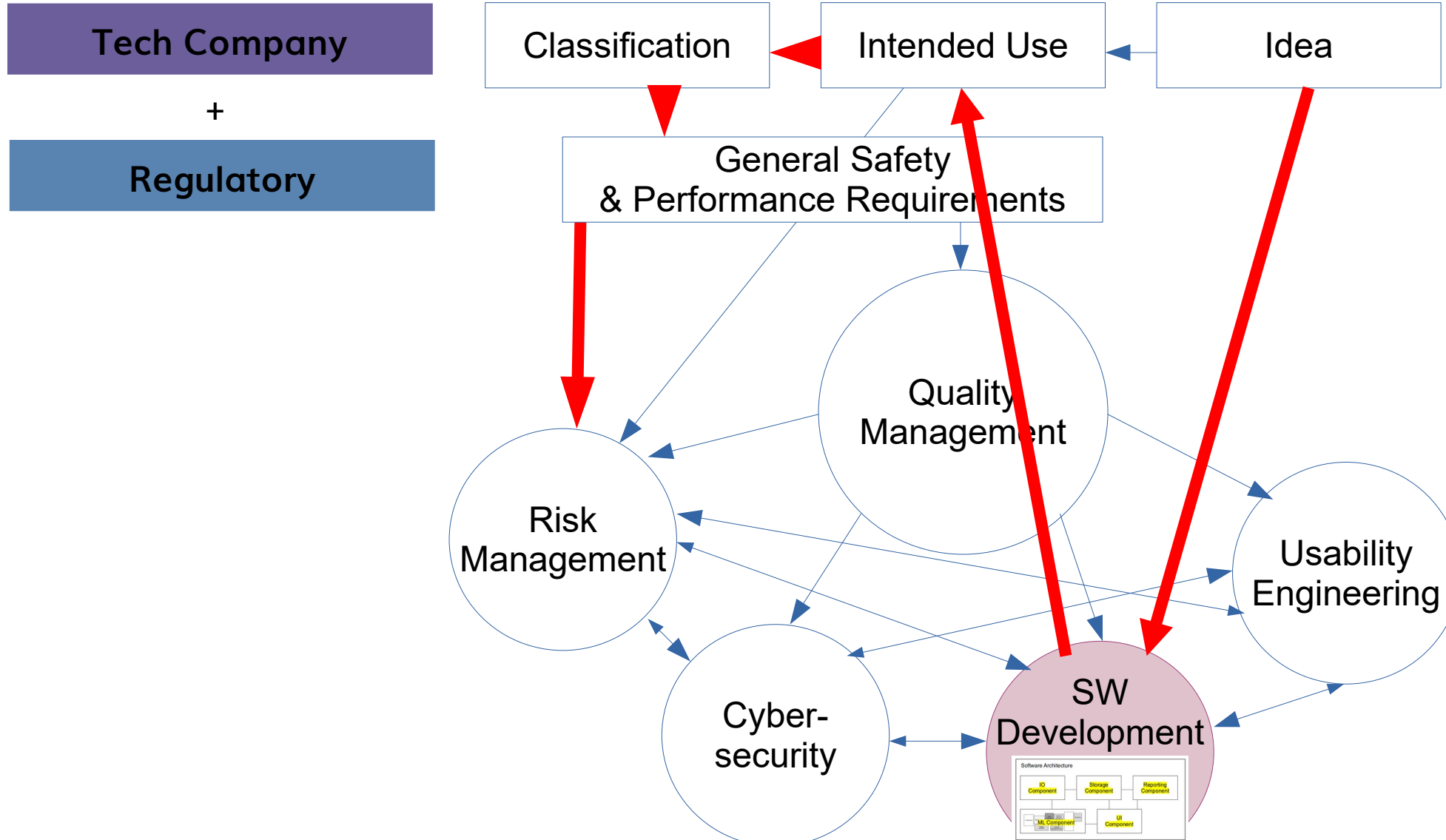
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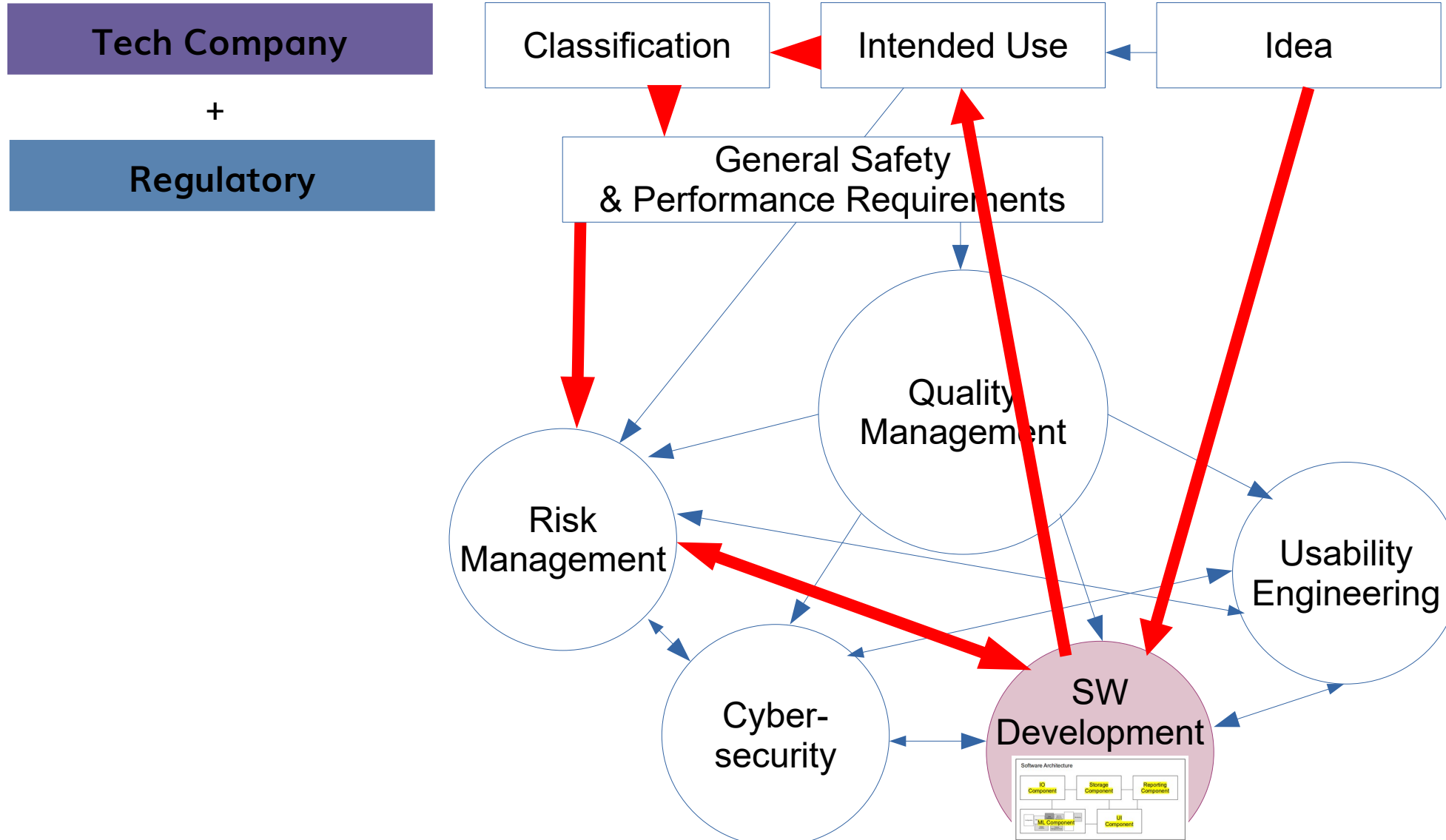
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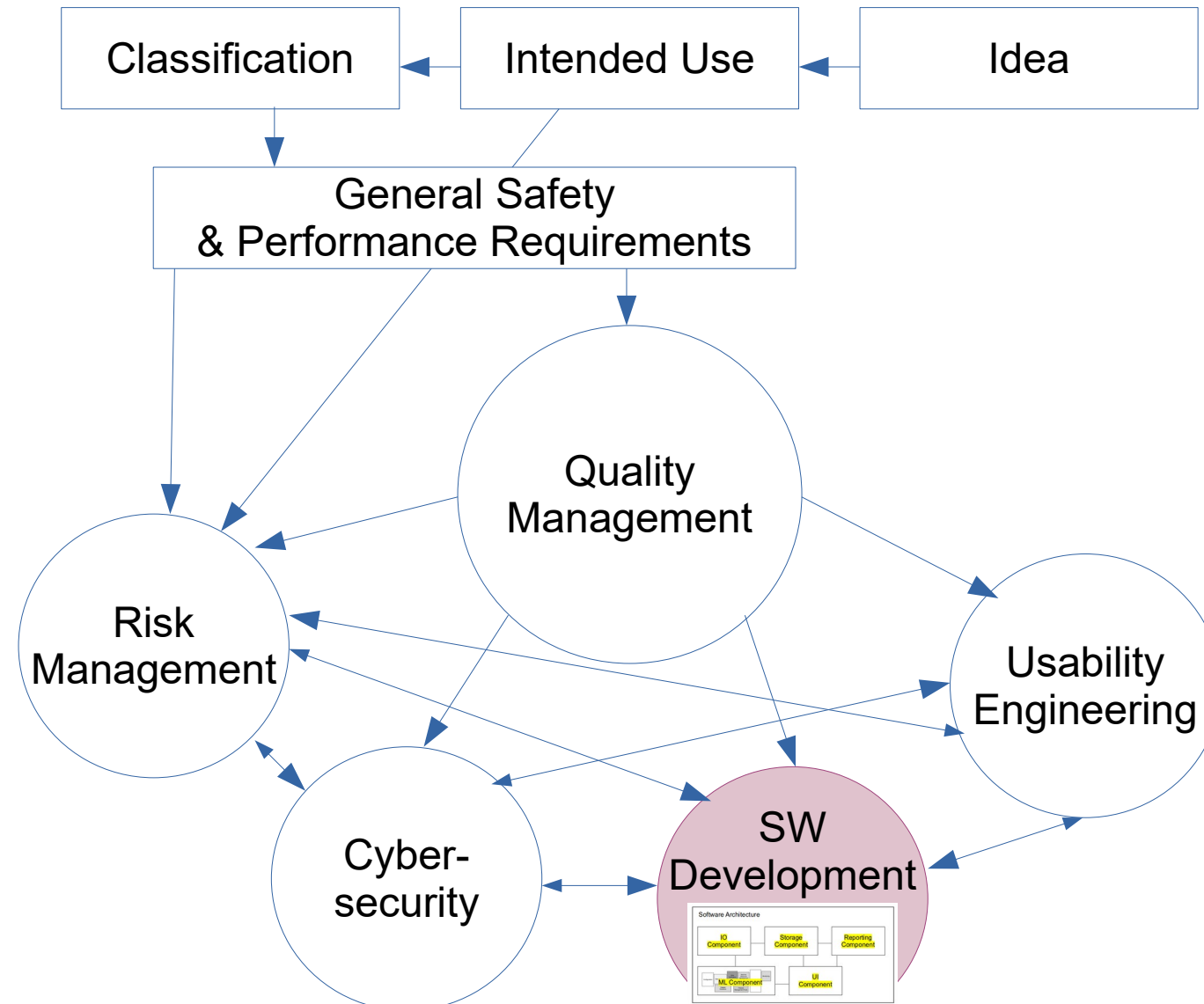




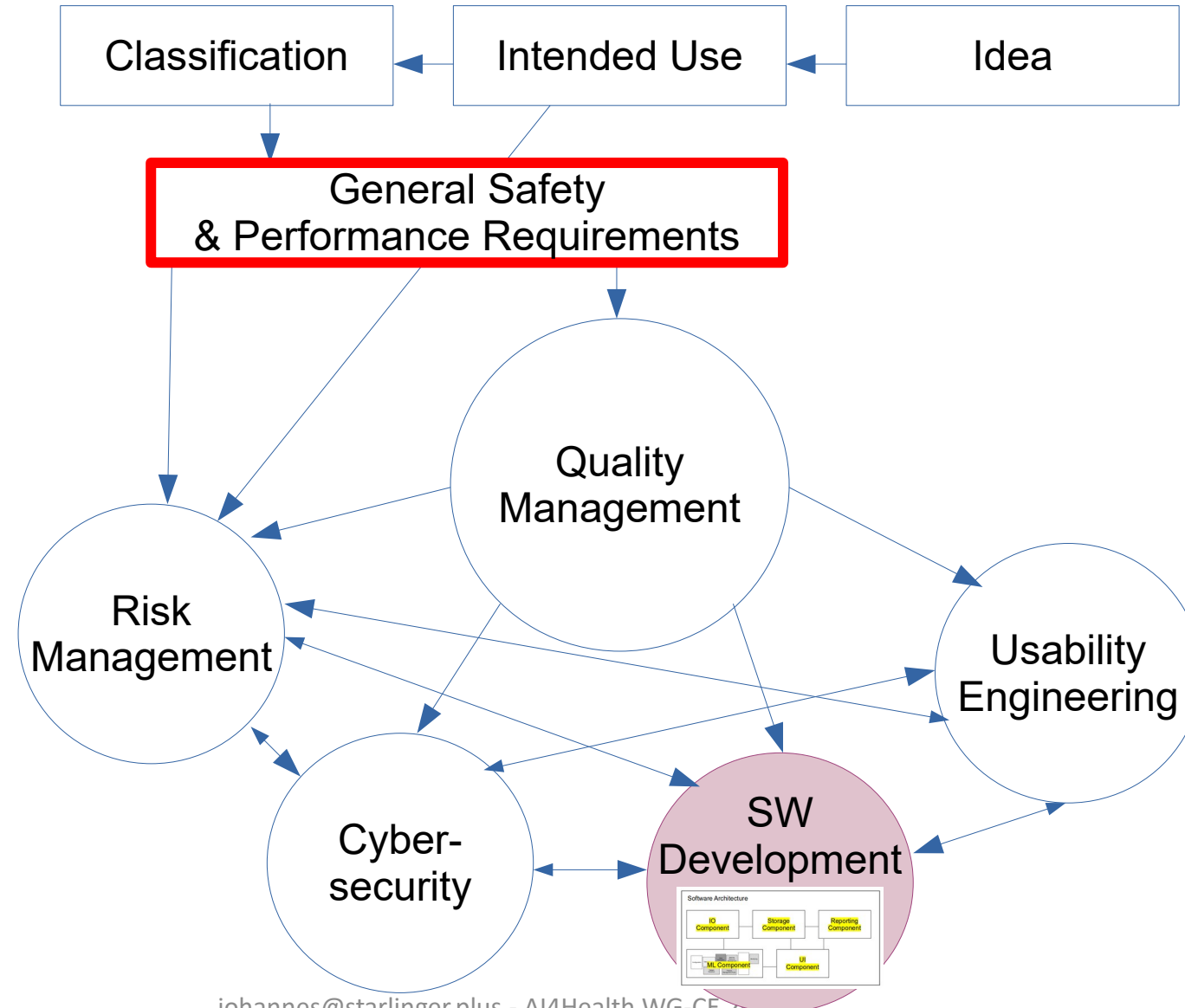
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What	Which application?	Which models? Which features? Which metrics? Which risks & mitigations?	Performance specification Risk & Classification	
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# AI in Context as SaMD



# AI in Context as SaMD



# Requirements for (AI as) SaMD



- **Proof of benefit and performance**
- **Verification and validation**
- **Assertion of reproducibility and reliability of results**
- **Description of methods and metrics used for the above**
- **Assertion of competence of involved personnel**

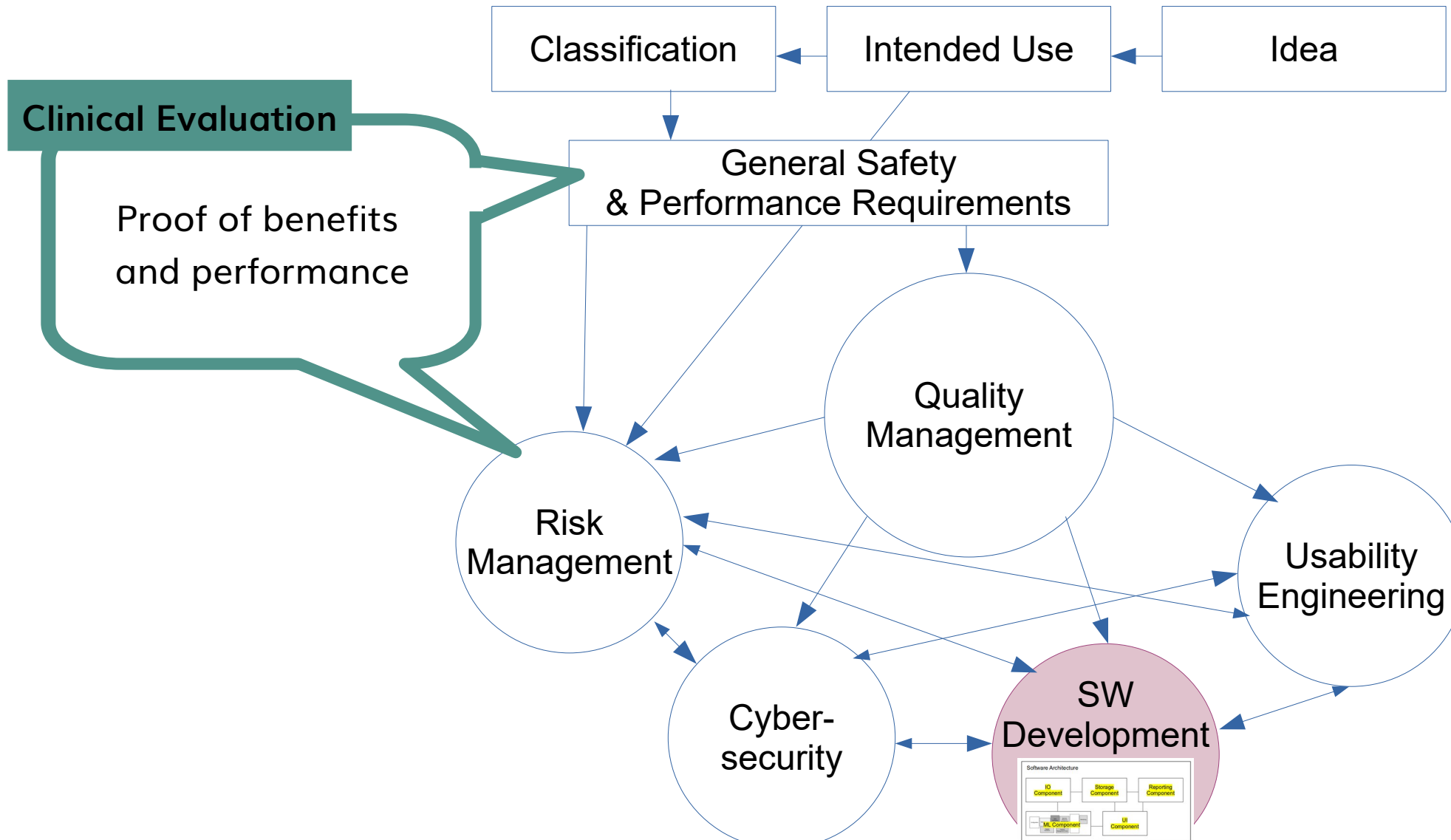
# Requirements for (AI as) SaMD

Clinical Evaluation!

- **Proof of benefit and performance**
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- Assertion of **reproducibility** and **reliability** of results
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What	Which application?	Which models? Which features? Which metrics? Which risks & mitigations?	Performance specification Risk & Classification	Evaluation metrics PICOs
Where	Which devices? Which market?	Which input? Which populations? How many datasets?	Device & input compatibility Target market	Included devices Study centers Countries
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Johannes Starlinger AI4Health WG-CE 10/2020	New market! New indication! New device!	More data? Other data? Other populations? New model?	Changes in - performance - input / types of input - intended use	Snapshot + Continuous? Drift?

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Why	Why	outcomes?	Benefit	Defined endpoints
What	Why Is the population in a target market different?	models? which features? Which metrics? Which risks & mitigations?	Performance specification Risk & Classification	Evaluation metrics PICOs
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	New market! New indication! New device!	More data? Other data Other populations New model?	Is the target market claim supported by the data? - types of input - intended use	Snapshot + Continuous? Drift?

Does the population match the data on site?

Does the study cover all target populations?

Is the population in a target market different?

Which market?

Which populations?

Target market

Study centers

Is the target market claim supported by the data?

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Which sites can perform the evaluation?

Do we have their populations covered?

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**Note:**  
This table highlights a selection of important aspects and topics but is non-exhaustive!

- In Healthcare
  - - Building AI Systems
  - - Regulatory Conformance
  - - Clinical Evaluation
- influence one another each way!