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LEVERAGING AI TO DRIVE AUTOMATION IN REGULATORY AND QUALITY MANAGEMENT

European Medical Device Summit | June 2025 | Markus Müller | Flinn.ai

Product Leader and Entrepreneur

- 15+ years in Tech & AI
- Product Head of N26 Bank – becoming the first European Bank to operate 100% on the cloud
- Co-Founder and CPO of Flinn.ai

Markus Müller

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Examples of industry - leading players who trust in Flinn to automate their QM/RA processes with AI

What do all leaders want?

Rich On Ibiza

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~~Rich On Ibiza~~

Return On Invest

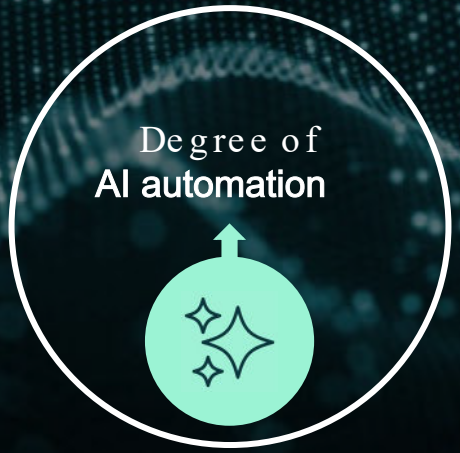
What do all leaders want?

~~Rich On Ibiza~~

Return On Invest

FINN

What has the highest return potential?



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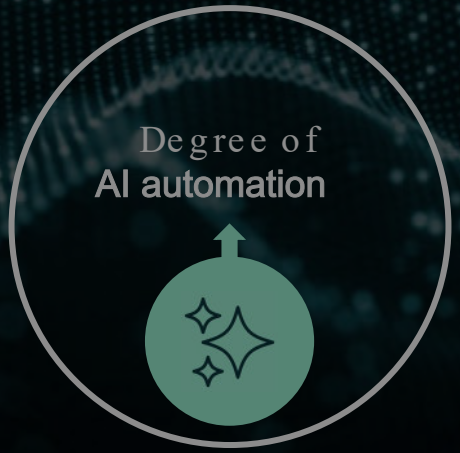

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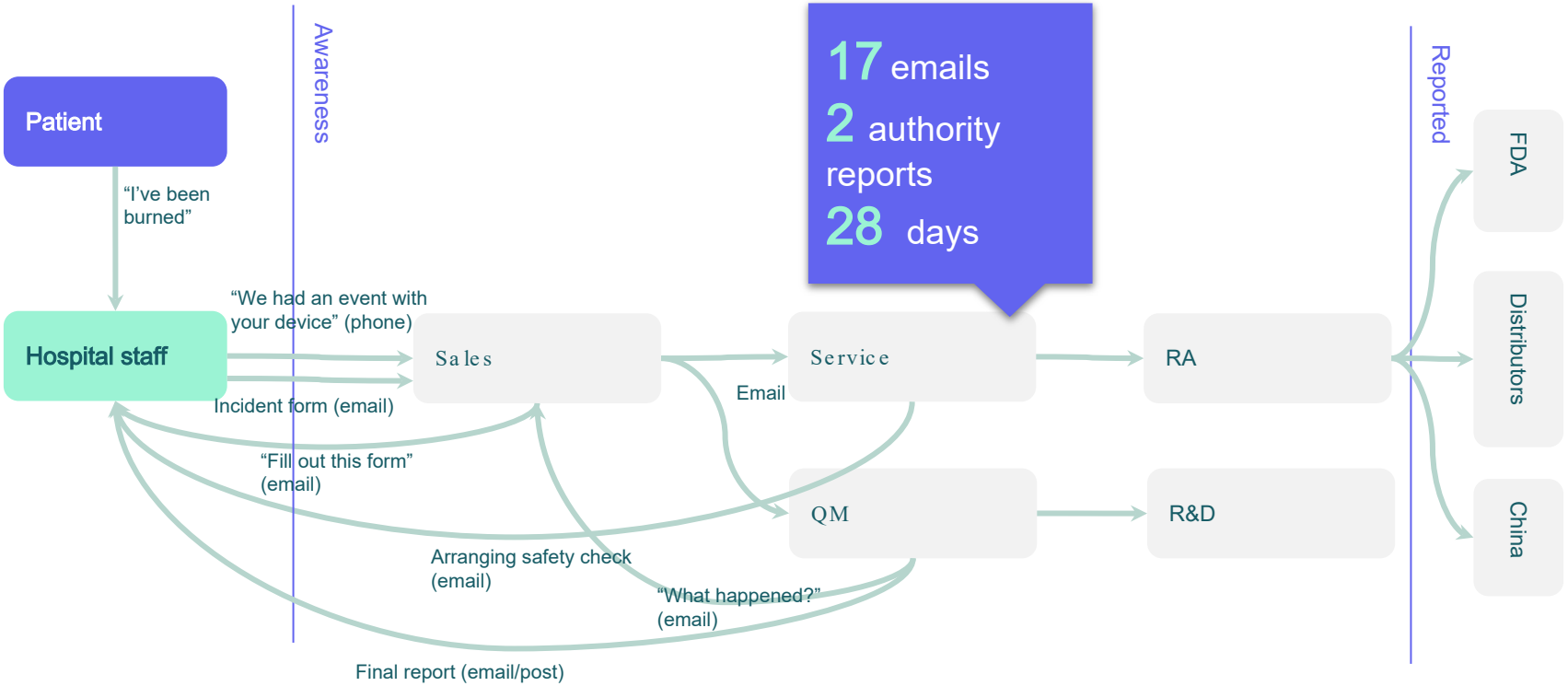
Complaint handling is a highly inefficient multi - player game



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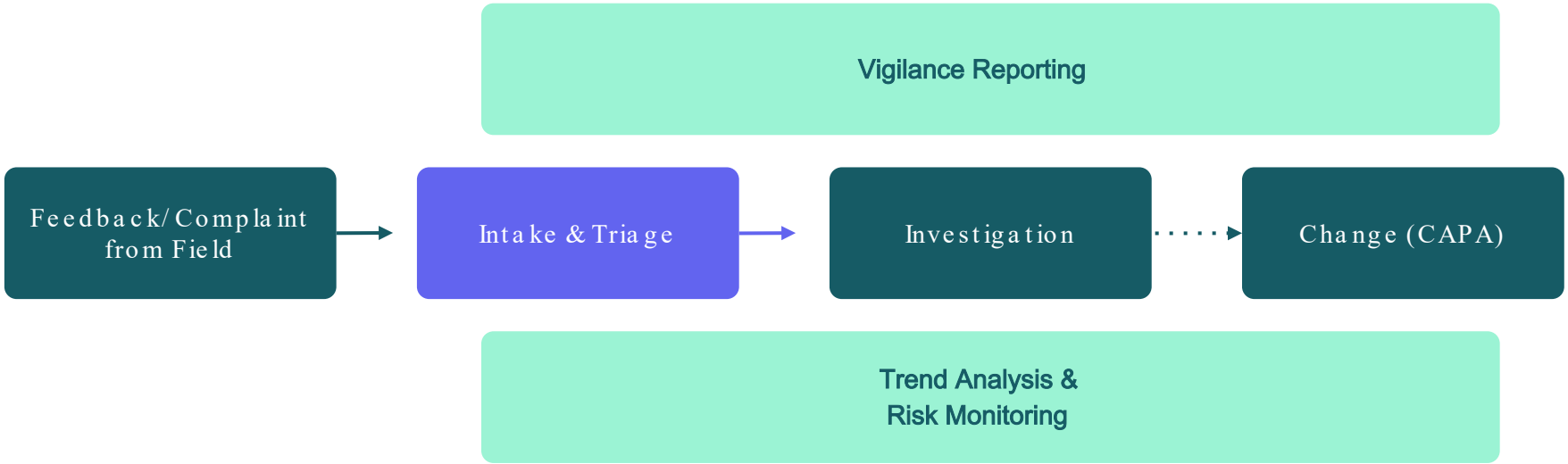
Low data quality as the blocker to drive automation



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Dynamic questionnaire generates targeted questions in real - time like a chatbot

Hello 👋 how can I help you, **Mr. Sales Rep** ?

Customer ABC received an implant component (Serial: 12345) in the wrong size during surgery.

Oh no. Was the packaging correct?

The packaging had the correct size, but the implant was too big for the others…

How was the situation resolved?

The surgeon tried another component unsuccessfully. This prolonged the surgery 30 min….

AI Categorization + Follow up questions

Batch number	1001
Severity	High
Reportable?	Yes
Device problem	Packaging Problem (A0205)
Internal code	157700
Patient	Procedural Complications (E21)

More details

Pre-drafted complaint report

Most ROI cases are limited to obvious factors

	Customer Service	QM	Sales / R&D
Obvious	Conversations per case	Time for documentation and trend reporting	Feedback for product development
Non-obvious	Consistency	Time to identify critical issues (trends/patterns)	Time spent on product problems, more on sales
	Training Cost	Traceability of change/CAPA impact	Repeating device problems
	Case resolution time	Time to identify root cause	
	Case prioritization	Time to identify new risks	

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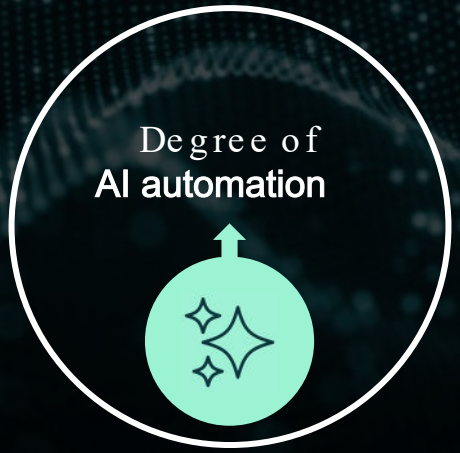

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Human vs. AI strengths

Strengths of Humans

- Nuanced judgment
- Accountability

Strengths of AI

- Consistency
- Speed & Scalability

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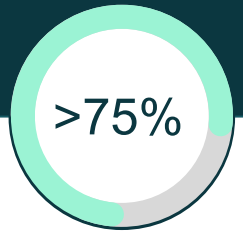
Expected potential of AI automation for selected processes



Safety Database Monitoring

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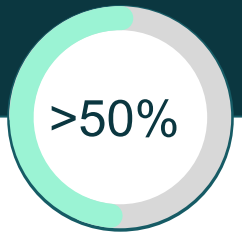
Regulatory Change Monitoring



End2End Complaint & Vigilance Handling

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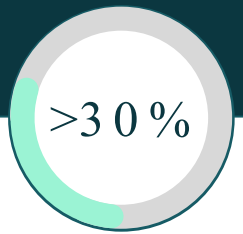
Clinical Literature Evaluation



Audit Management

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Change Management


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Return on Invest
Make - or - Buy?

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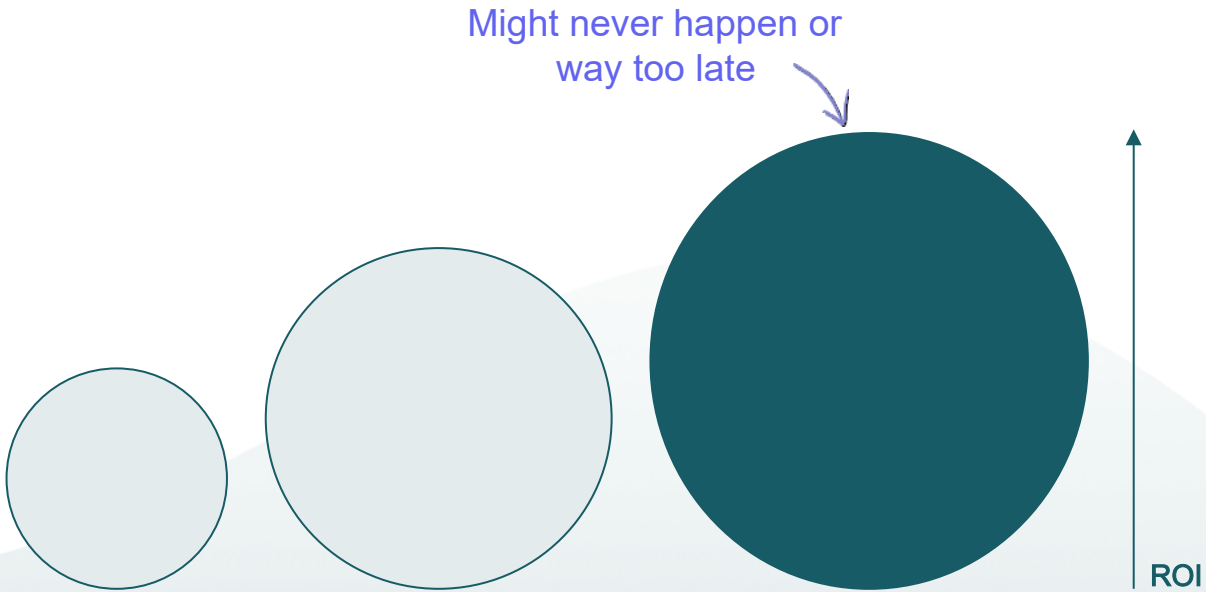
“Agility and focus is becoming a driving factor for Make - or - Buy decisions”

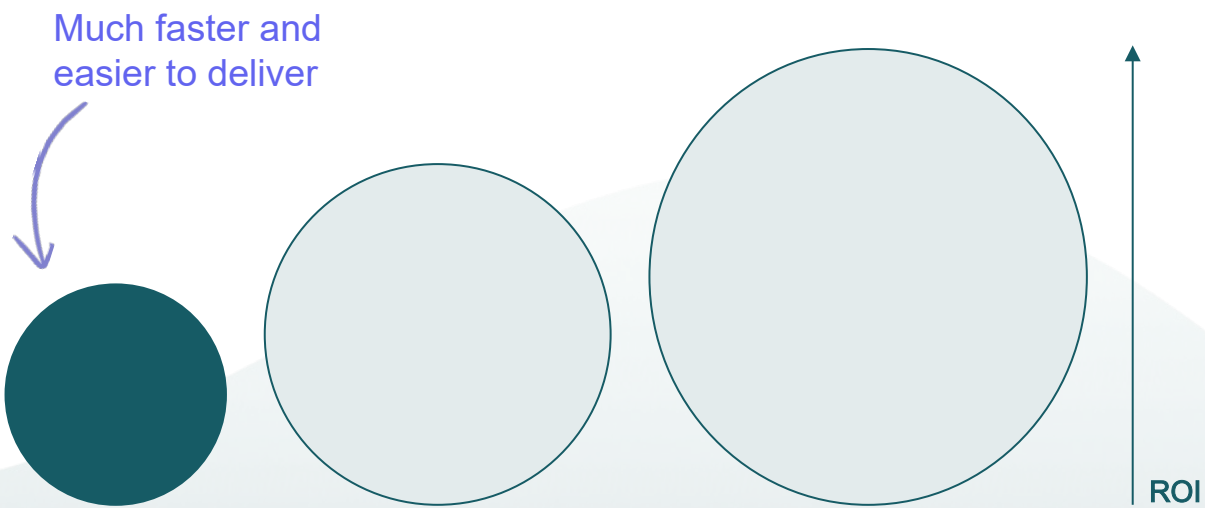
What case shall we pick?

BUT

Change effort and complexity might kill your high potential use case



Start simple
→ learn
→ deliver
ROI
→ repeat



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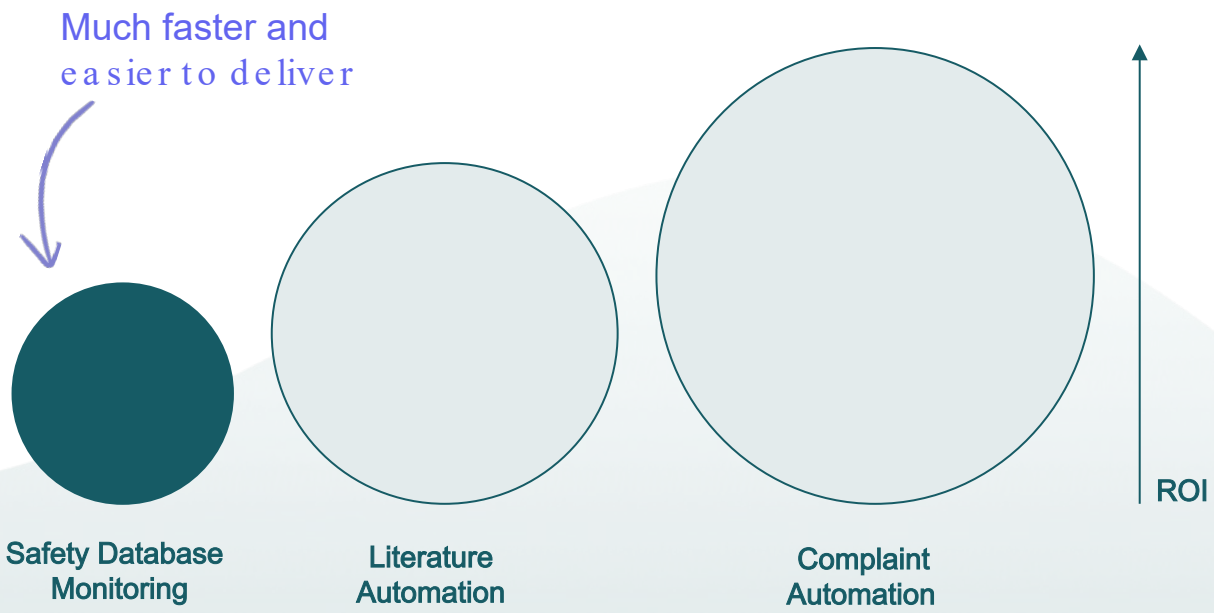

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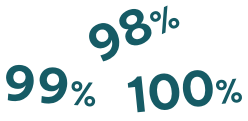
Key challenges of getting AI automation rolled - out

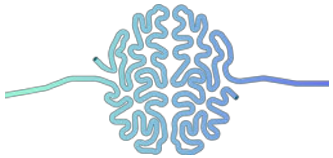


Expectations
vs. AI accuracy

Validation
of AI features

Experience in purchasing
SaaS/AI software

Data concerns
lack of trusted partner



IT integrations significantly
increasing complexity

Fast change
in AI- Technology

Join our webinar on AI agents for QM/RA automation

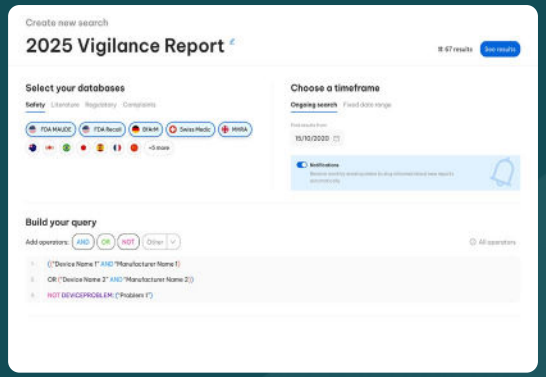
4th of September, 5pm CET

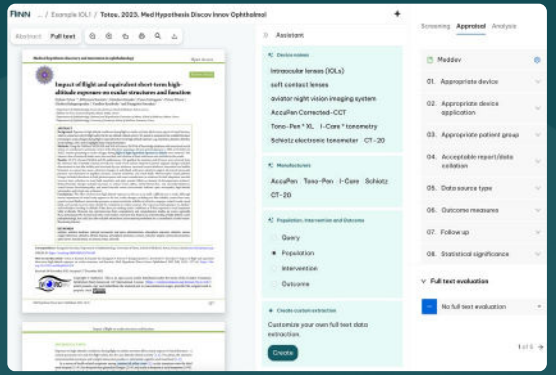
- Learn what an AI agent is
- Learn about strengths and weaknesses
- What use cases could become interesting in the next 12 - 24 months

Exclusive **only for leaders & executives** of medical device manufacturers !

Register here

AI- enabled
Safety DB
Monitoring





AI- enabled
Literature
Evaluation

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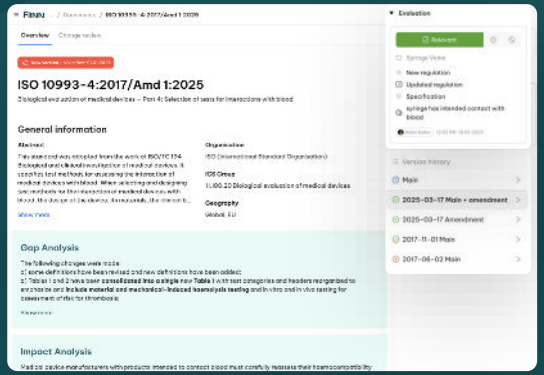
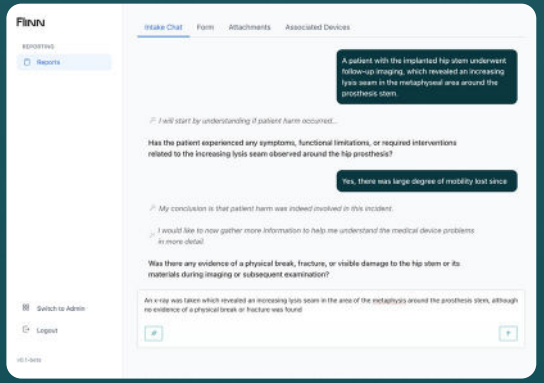
Platform



AI- enabled
Regulatory
Monitoring



AI- enabled
Complaint
Data Handling

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CPO and Co-Founder

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Want to know more about AI automation?

Let‘s talk! You can find me at booth #10

1 min Feedback:
Please pull out your phone