

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

CUSTOMERS

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

What do all leaders want?

~~Rich On Ibiza~~

Return On Invest

What do all leaders want?

~~Rich On Ibiza~~

Return On Invest

What has the highest return potential?

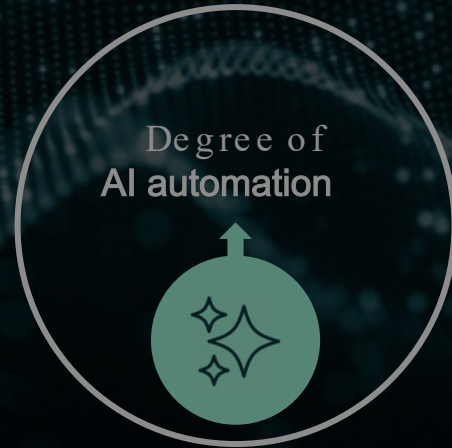
Use cases with highest potential



Degree of AI automation

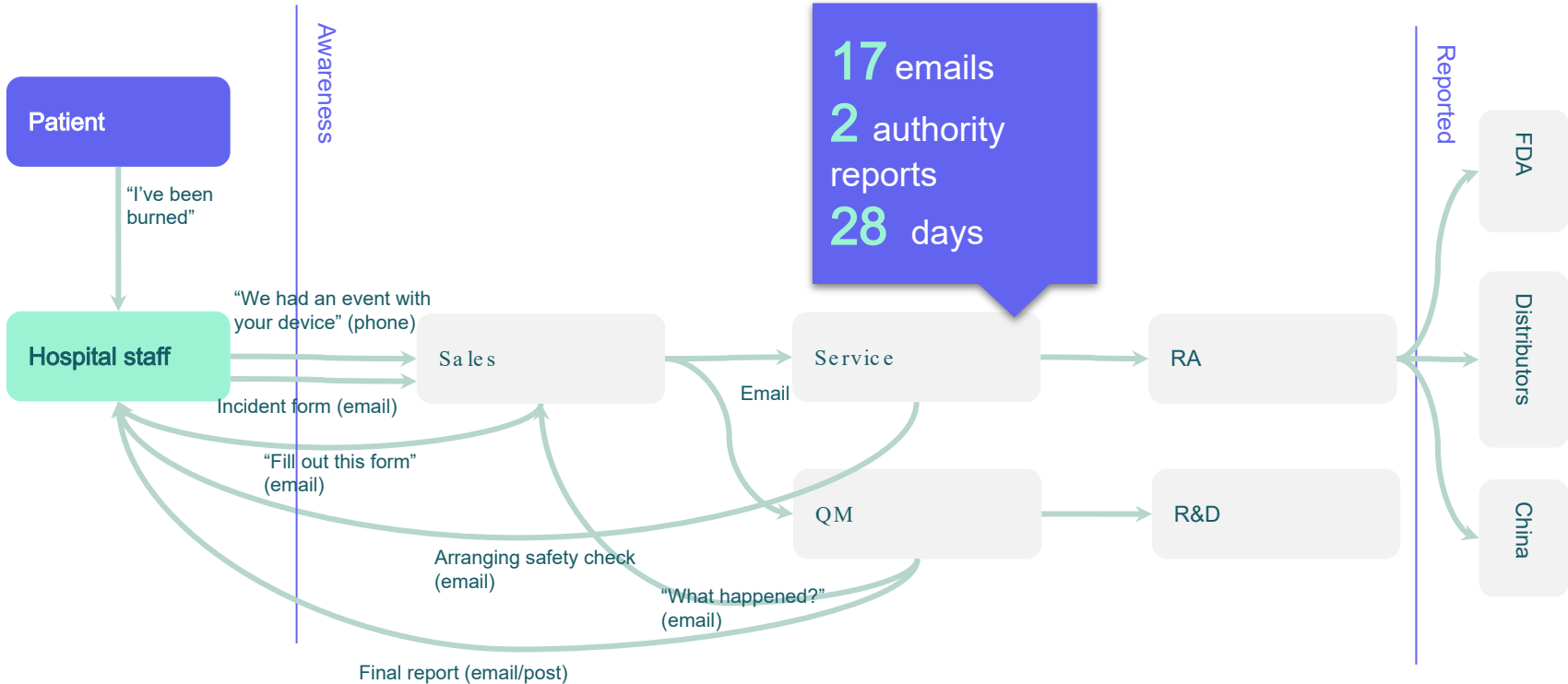


What has the highest return potential?



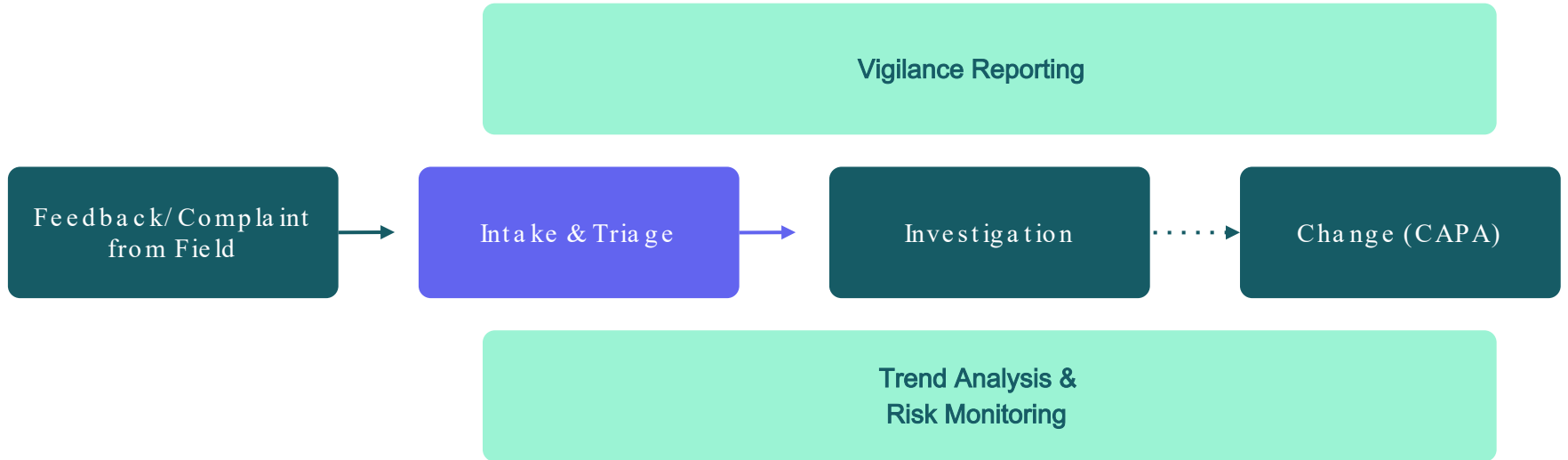
Assessing process potential

Complaint handling is a highly inefficient multi - player game



Assessing process potential

Low data quality as the blocker to drive automation



Assessing process potential

Dynamic questionnaire real - time like a chatbot

generates targeted questions in

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)

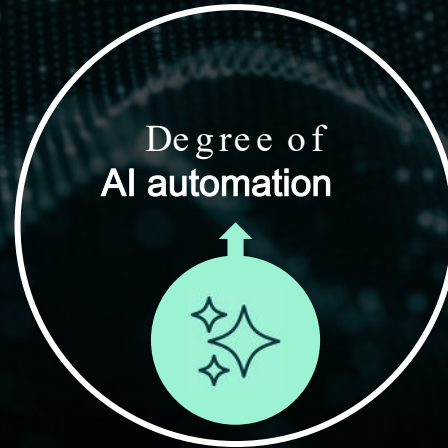
More details

Pre-drafted complaint report

Most ROI cases are limited to obvious factors

	Customer Service	QM	Sales / R&D
Obvious	<ul style="list-style-type: none"> ↓ Conversations per case 	<ul style="list-style-type: none"> ↓ Time for documentation and trend reporting 	<ul style="list-style-type: none"> ↑ Feedback for product development
Non-obvious	<ul style="list-style-type: none"> ↑ Consistency 	<ul style="list-style-type: none"> ↓ Time to identify critical issues (trends/patterns) 	<ul style="list-style-type: none"> ↓ Time spent on product problems, more on sales
	<ul style="list-style-type: none"> ↓ Training Cost 	<ul style="list-style-type: none"> ↑ Traceability of change/CAPA impact 	<ul style="list-style-type: none"> ↓ Repeating device problems
	<ul style="list-style-type: none"> ↑ Case resolution time 	<ul style="list-style-type: none"> ↓ Time to identify root cause 	
	<ul style="list-style-type: none"> ↑ Case prioritization 	<ul style="list-style-type: none"> ↓ Time to identify new risks 	

What has the highest
return potential?



Human vs. AI strengths

Strengths of Humans

Nuanced judgment

Accountability

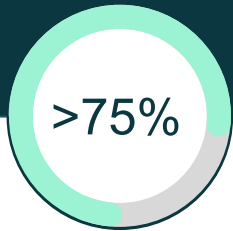


Strengths of AI

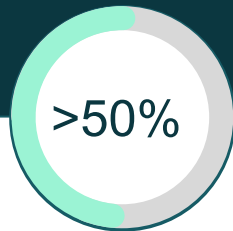
Consistency

Speed & Scalability

Expected potential of AI automation for selected processes



Safety Database Monitoring
—
Regulatory Change Monitoring



End2End Complaint & Vigilance Handling
—
Clinical Literature Evaluation



Audit Management
—
Change Management

Return on Invest

Make - or - Buy?

“

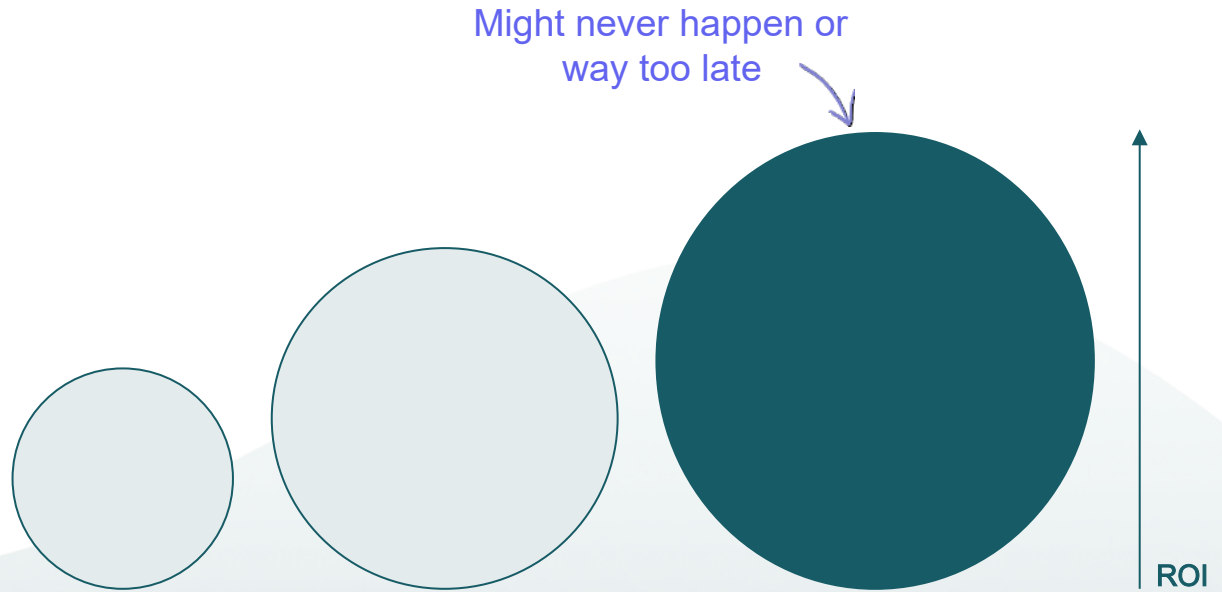
Agility and focus is becoming
a driving factor for Make - or -
Buy decisions”

What case
shall we
pick?



BUT

Change
effort and
complexity
might kill
your high
potential
use case



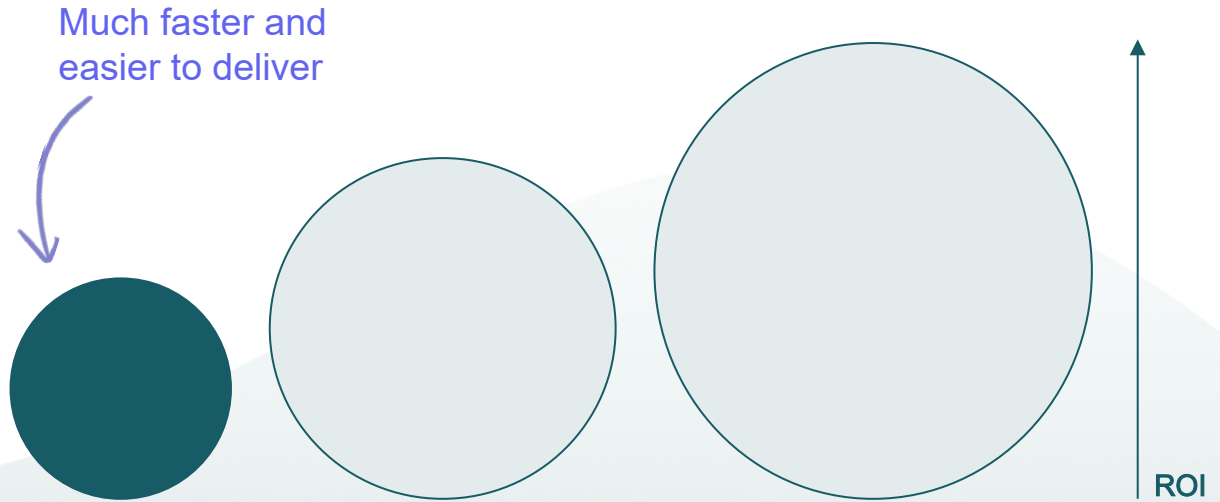
Start simple

→ learn

→ deliver

ROI

→ repeat



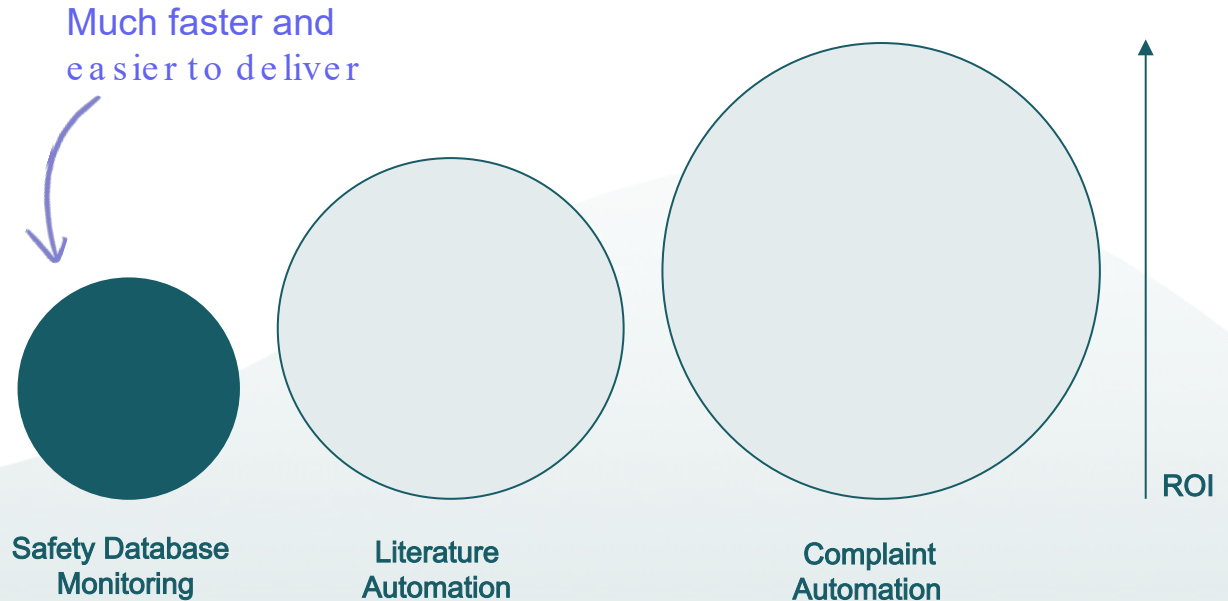
Start simple

→ learn

→ deliver

ROI

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Key challenges of getting AI automation rolled - out

98%
99% 100%

Expectations
vs. AI accuracy



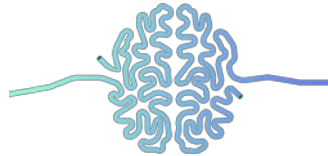
Validation
of AI features



Experience in purchasing
SaaS/AI software



Data concerns
lack of trusted partner



IT integrations significantly
increasing complexity

**ML GenAI
AI Agent**

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

Create new search

2025 Vigilance Report

8/27 results [See results](#)

Select your databases

Safety [Literature](#) [Regulatory](#) [Complaints](#)

[FDA MDRs](#) [FDA Recall](#) [OSHA](#) [Device Recall](#) [IRRA](#)

Choose a timeframe

From: 12/30/2020 To: 12/30/2025

Build your query

Add operators: [AND](#) [OR](#) [NOT](#) [Other](#)

1. ("Device Name 1" AND "Manufacturer Name 1")

2. OR ("Device Name 2" AND "Manufacturer Name 2")

3. NOT DEVICEPROBLEM ("Problem 1")

Flinn Platform

AI-enabled Regulatory Monitoring

Flinn / [Home](#) / [Reports](#) / [809 9934 - 4:2017/Amd 1:2025](#)

Overview [Change table](#)

[Checklist](#) [Add filter](#) [Add column](#)

ISO 10993-4:2017/Amd 1:2025

Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood

General information

Reference	ISO 10993-4:2017/Amd 1:2025
Organization	ISO (International Standard Organization)
ISO Group	ISO/TC 212 (Biological evaluation of medical devices)
Geography	Global, EU

Deep Analysis

The following changes were made:

- Some definitions have been revised and new definitions have been added.
- Table 1 (1.2.2) has been transferred to a separate table in other categories and headers reorganized to include material and mechanical-induced hemolysis testing and in-vitro and in-vivo testing for statements related to thrombosis.

Impact Analysis

Full on-site review of all devices intended to contact blood must comply, however that have compliance by

AI-enabled Literature Evaluation

Flinn / [Home](#) / [Reports](#) / [Topic: 2025_MedHypothesis Device Involvement](#)

Abstract [Full text](#)

Topic of light and equivalent short-term high-attitude exposure on ocular structures and function

Abstract

Introduction: Contact lenses (CLs) are used to correct refractive errors and provide visual clarity. However, prolonged use of CLs may lead to ocular discomfort and potential damage to the eye. This study aims to investigate the effects of light and equivalent short-term high-attitude exposure on ocular structures and function.

Methods: A cohort of 20 participants was recruited and divided into two groups: a control group and an experimental group. The experimental group wore CLs for 8 hours per day for 4 weeks. The control group did not wear CLs. The participants were subjected to a series of tests to measure ocular parameters, including intraocular pressure (IOP), corneal thickness, and visual acuity.

Results: The results showed that the experimental group had significantly higher IOP and corneal thickness compared to the control group. There was also a significant decrease in visual acuity in the experimental group. These findings suggest that prolonged use of CLs may lead to ocular discomfort and potential damage to the eye.

Conclusion: The results of this study indicate that prolonged use of CLs may lead to ocular discomfort and potential damage to the eye. Further research is needed to investigate the underlying mechanisms and to develop strategies to mitigate these effects.

Assistant

- Introduce lenses (CLs)
- soft contact lenses
- ovular/light vision imaging system
- AccuFlex Connected-CCT
- Tono-Pen XL, I-Care tonometry
- Schiotz electronic tonometer
- CT-20

Full-text evaluation

1. Appropriate device
2. Appropriate device application
3. Appropriate patient group
4. Accessible report/links available
5. Data source type
6. Outcome measures
7. Follow-up
8. Statistical significance

[No full-text evaluation](#)

AI-enabled Complaint Data Handling

Flinn / [Home](#) / [Reports](#) / [809 9934 - 4:2017/Amd 1:2025](#)

Overview [Change table](#)

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Intake Chat [Form](#) [Attachments](#) [Associated Devices](#)

REPORTS

[Reports](#)

A patient with the implanted hip stem underwent follow-up imaging, which revealed an increasing lysis seen in the metaphyseal area around the prosthesis stem.

I will start by understanding if patient harm occurred...

Has the patient experienced any symptoms, functional limitations, or required interventions related to the increasing lysis seen around the hip prosthesis?

Yes, there was large degree of mobility lost since

My conclusion is that patient harm was indeed involved in this incident.

I would like to now gather more information to help me understand the medical device problems in more detail.

Was there any evidence of a physical break, fracture, or visible damage to the hip stem or its materials during imaging or subsequent examination?

An x-ray was taken which revealed an increasing lysis seen in the area of the metaphysis around the prosthesis stem, although no evidence of a physical break or fracture was found.



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Want to know more about [AI automation?](#)

Let's talk! You can find me at [booth #10](#)



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