

OPTIMIZING DESIGN, SAFETY AND EFFICIENCY WITH ARTIFICIAL INTELLIGENCE

Dr. Richard Willmann

Image Guided Therapy Systems, Philips

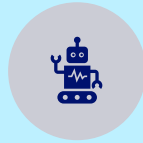
June 3rd, 2025

PHILIPS

Executive summary



AI is integrated in many medical devices, and the FDA has approved more than 950 over the past 10 years



In the past 3 years, AI is increasingly also used to streamline the R&D process itself



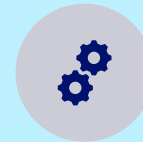
More than 50% of med tech companies have not yet realized value from AI in the R&D process



AI in R&D will lead to about 20% cost reduction and a similar time-to-market speed up within 3 years



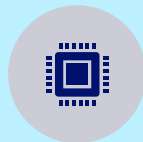
There are hundreds of use cases, thousands of vendors and not one encompassing tool chain



Example use cases include ideation, SW co-creation, knowledge management, generative HW design optimization, risk management and complaint handling, training material creation



The most successful implementation plans will include process redesign and require technology partners



AI in R&D will not provide a sustainable competitive advantage, but be a necessity, like the introduction of PCs in the 1980s

Not all types of AI are used in FDA approved medical devices

AI tools used for R&D include also generative AI and Large Language Models



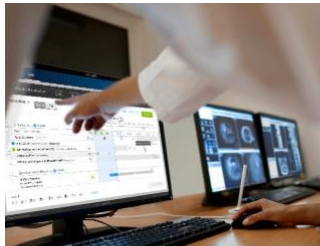
Smart patient monitoring

Enabling timely care interventions



Radiology Operations Command Center

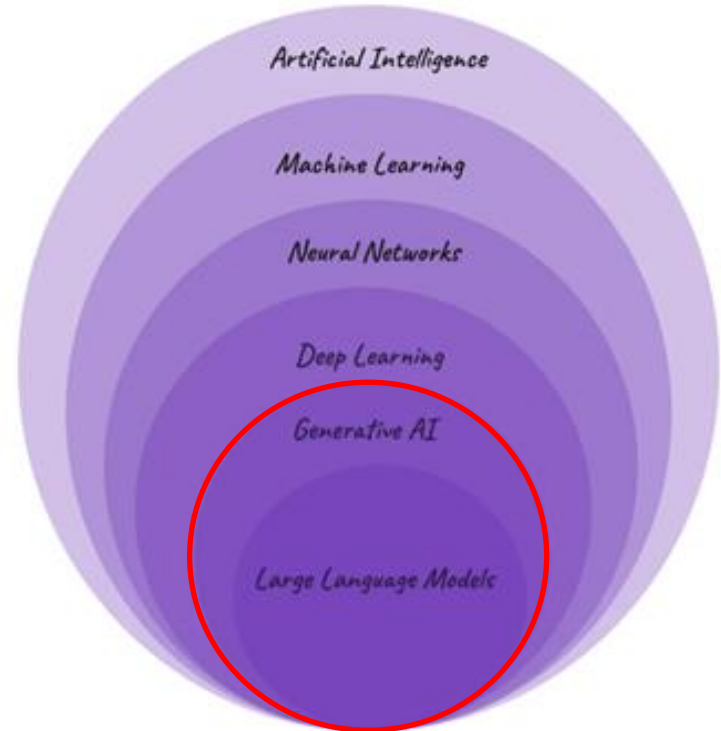
Connecting imaging experts at a central command center with onsite staff for virtual support



Tasy EMR AI Virtual Assistant can help streamline the charting and ordering process to save clinicians valuable time

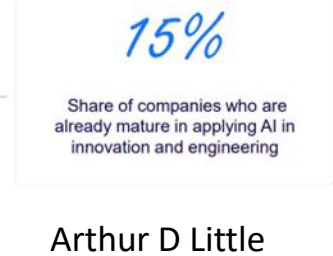


MR SmartSpeed can increase imaging speed by up to a factor 3 while providing up to 65% greater image resolution



Most med tech companies have not yet seen value created by AI in R&D, but expect significant efficiencies in the next 3 years

State of adoption



Size of the prize

Type of costs	Top 10 medtech firm average cost ¹	Potential savings % from use of AI in the next 2-3 years ²	Potential savings estimate	Functional areas likely to benefit
Selling, general and administrative costs (SG&A)	\$7.2B	7%-19%	\$0.5B - \$1.5B	Commercial, Shared services
Cost of goods sold (COGS)	\$11.7B	5%-12%	\$0.6B - \$1.4B	Supply chain and manufacturing
R&D costs	\$1.5B	7%-20%	\$0.1B - \$0.3B	Product development
Estimated potential savings for a large medtech company in the next 2-3 years			\$1.2B - \$3.2B	

Deloitte



The FDA has adopted generative AI for their own work

FDA uses a customized ChatGPT based model that is running on a private server

FDA NEWS RELEASE

FDA Announces Completion of First AI-Assisted Scientific Review Pilot and Aggressive Agency-Wide AI Rollout Timeline

For Immediate Release: May 08, 2025

In a historic first for the agency, FDA Commissioner Martin A. Makary, M.D., M.P.H., today announced an aggressive timeline to scale use of artificial intelligence (AI) internally across all FDA centers by June 30, 2025, following the completion of a new generative AI pilot for scientific reviewers.

“I was blown away by the success of our first AI-assisted scientific review pilot. We need to value our scientists’ time and reduce the amount of non-productive busywork that has historically consumed much of the review process. The agency-wide deployment of these capabilities holds tremendous promise in accelerating the review time for new therapies,” said Dr. Makary.

With hundreds of possible use cases for AI in R&D across the whole life-cycle, companies need to choose use cases wisely

Database of AI / complementary technology use cases

7 Use Case: AI-Powered Test Automation

Description
Automate test case creation and execution with AI in CI/CD pipelines, ensuring new software and features meet quality standards, reducing errors and minimizing manual testing requirements. E.g. unit tests to ensure core logic functions act as expected, identifying issues early in the development process.

Personas
Software engineers

Pain/Gain Points Solved

- Complexity and manual effort of debugging software
- Difficult to transition to a CI/CD way of working
- Automated test creation and debugging tools

Solution

Initial estimate of implementation effort:

- Duration: Unknown
- Team: Requires a cross-functional team
- Need better understanding of testing processes (including physical tests) prior to effort estimation

Example vendors:

Testim, CircleCI, Cobot

9,000+ Vendors and their AI / complementary technology solutions screened

900+ Use cases generated based on technology solutions and vendors mapped to personas

Each use case with detailed technical solution, example vendors, jobs, pain and gain points of the responding persona

Arthur D Little

Exhibit 3 | 15 Use Cases Should Be Priorities for Medtech Companies

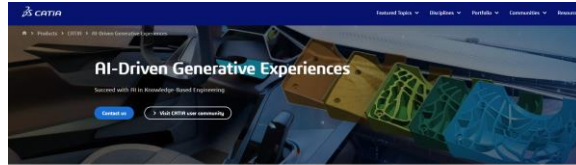
Research and development	Operations	Marketing and sales	After-sales and customer support	Corporate functions and collaboration
Automated software code generation and documentation ★	Automated quality assurance (esp. for novel processes) ★	Next-best action and preparation for sales reps ★	Customer support bots (external) ★	Advanced knowledge management ★
Generative product design ★	Supplier evaluation and negotiation preparation ★	Automatic creation of tender documents ★	Customer service rep administrative support (internal) ★	GenAI enabled software applications ★
Support with regulatory filings or clinical trial reporting ★	Dynamic supply chain simulation and optimization ★	Personalized proactive outreach and campaigns ★	Product education and continuous learning ★	Simplified data analytics (natural language-based) ★

★ Rapid implementation potential ★ High potential impact

Source: BCG analysis.

Boston Consulting Group

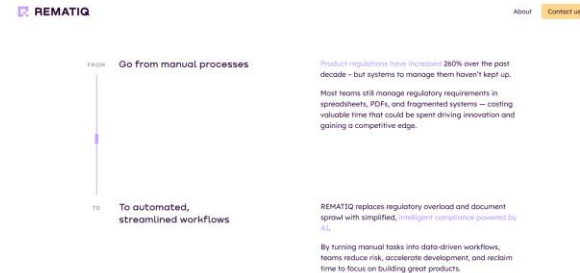
Several AI vendors are exhibiting on the European Medical Device summit



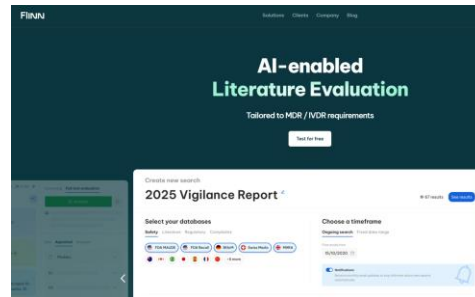
Enhance Your Capabilities with Generative AI

- Generative Artificial Intelligence (AI) has emerged as a groundbreaking tool for designers and engineers, offering **unprecedented capabilities** to create new design concepts, optimize product performance, and accelerate time-to-market. CATIA's AI-driven capabilities offer a **powerful development time and time to market**, based on models developed from industry-specific data, generated from knowledge and know-how of industry processes. Your productivity, risk and time-to-market can be significantly reduced.
- Enhanced Performance to generate higher performance designs
 - Reduction of the time to market up to 300%
 - Management of a large number of requirements while controlling investment cost
 - Reduction of inventory costs by 30%
 - Generation time for manufacturing simulation up to 80%

Dassault: generative HW design



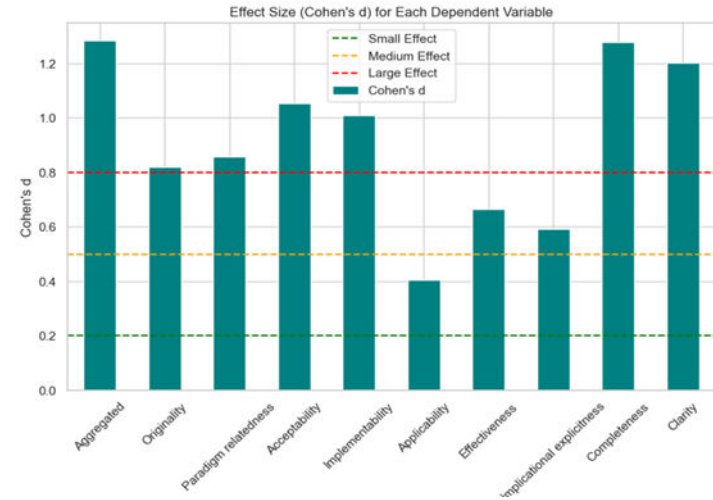
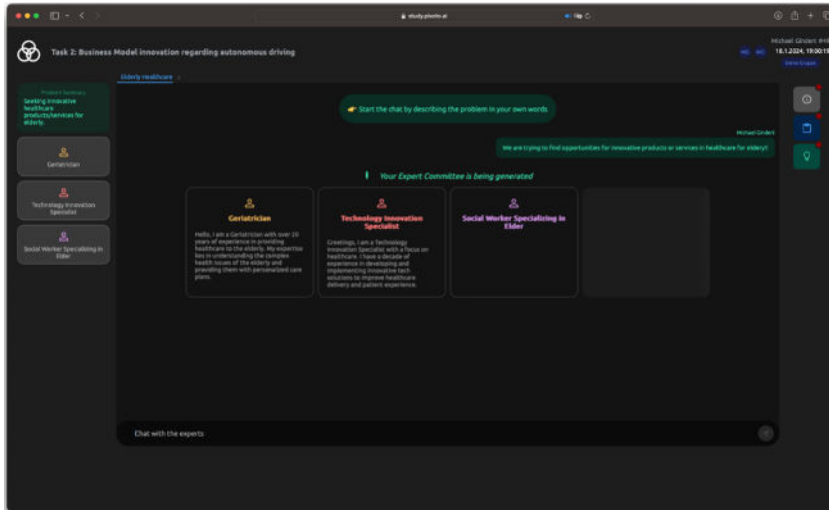
Rematiq: norm compliance and requirements



Flinn: AI-enabled regulatory document creation

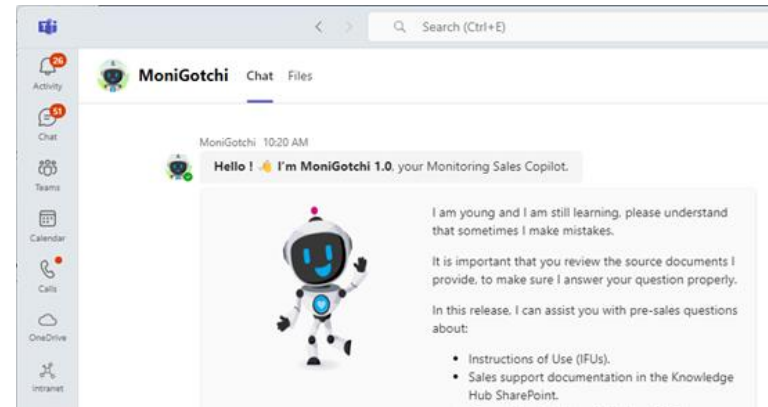
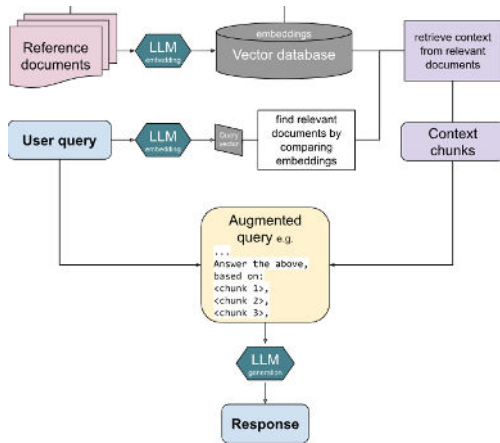
AI-augmented teams are better in ideation and brainstorming

Scientific experiment by University of Regensburg demonstrates the value of generative AI 'team members'



AI can make legacy knowledge accessible to all employees

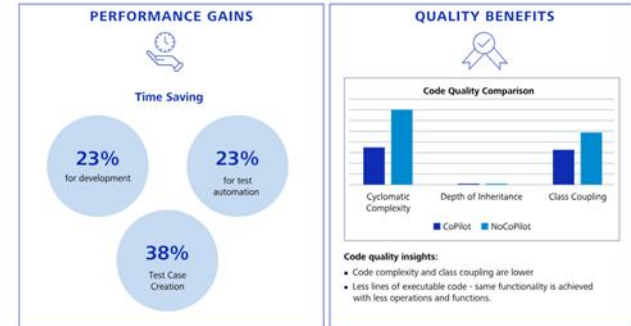
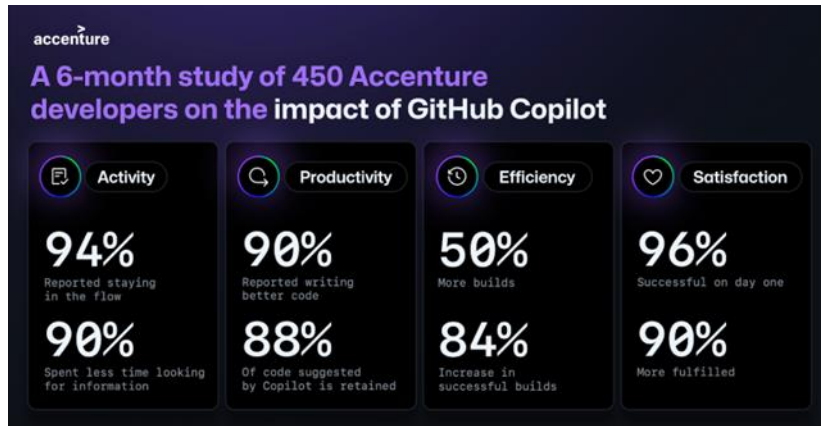
Using a private LLM version in combination with a document archive (medical device DHF)



Wikipedia: Retrieval Augmented Generation

GitHub Copilot is increasing the efficiency of SW developers

Results reported from actual deployments differ widely



Conclusion

In conclusion, our study has demonstrated that the implementation of Microsoft GitHub Copilot can lead to

10% - 15 %

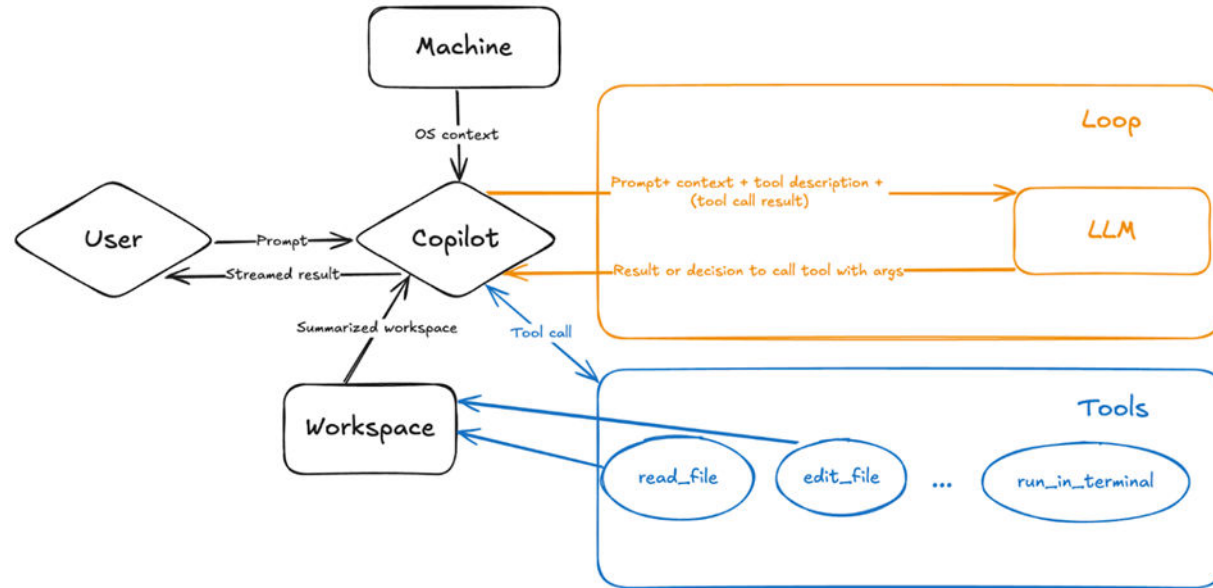
overall performance gain per developer

GitHub Copilot

Zeiss

GitHub Copilot just introduced an agentic AI version

Goal driven agents, once given a goal, can plan steps, take actions, learn from results and improve



Github Copilot

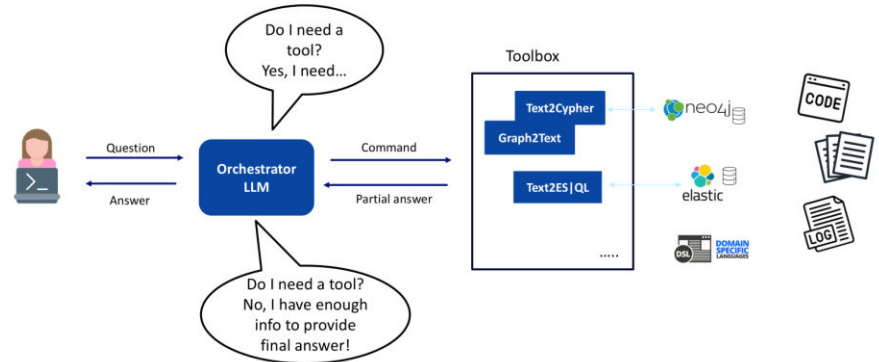
AI assists the CAPA process

PPP with TNO-ESI aims to develop an AI-powered, trustworthy assistant

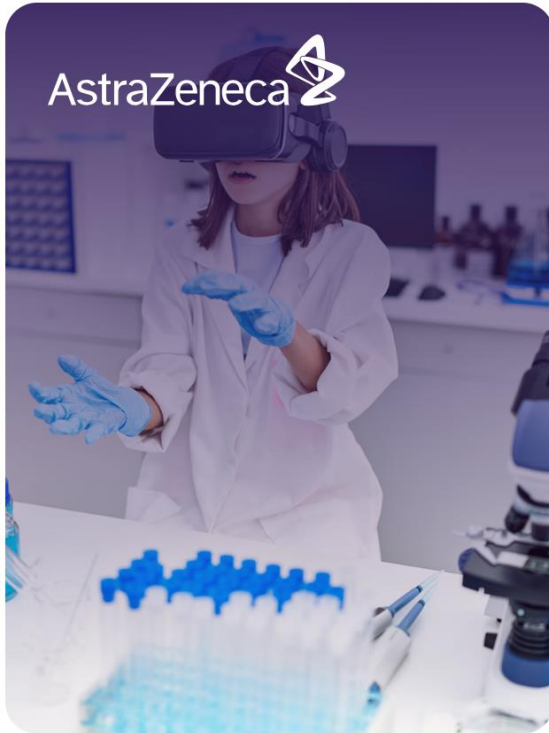
7 Complaints and Adverse Events related to the Safety Risk or Noncompliance Issue	
Complaint Search Window:	TrackWise search from 01 Oct 2020 until 30 Jun 2023. This is a standardized time frame from the complaint handling unit.
Methodology:	A keyword search on 'line', 'collimator' and 'shutter' was performed on the following TrackWise fields: Description, Notes, Communication, Problem, Investigation, Evaluation, Action, Software Revision. Further filtering was applied to exclude complaints where 'line' was unrelated to collimation.
Results:	
Number of Complaints:	9
Injuries Reported by country / region:	0



DELPHI 2024 is looking to automate this step from the IIA report, by using GenAI

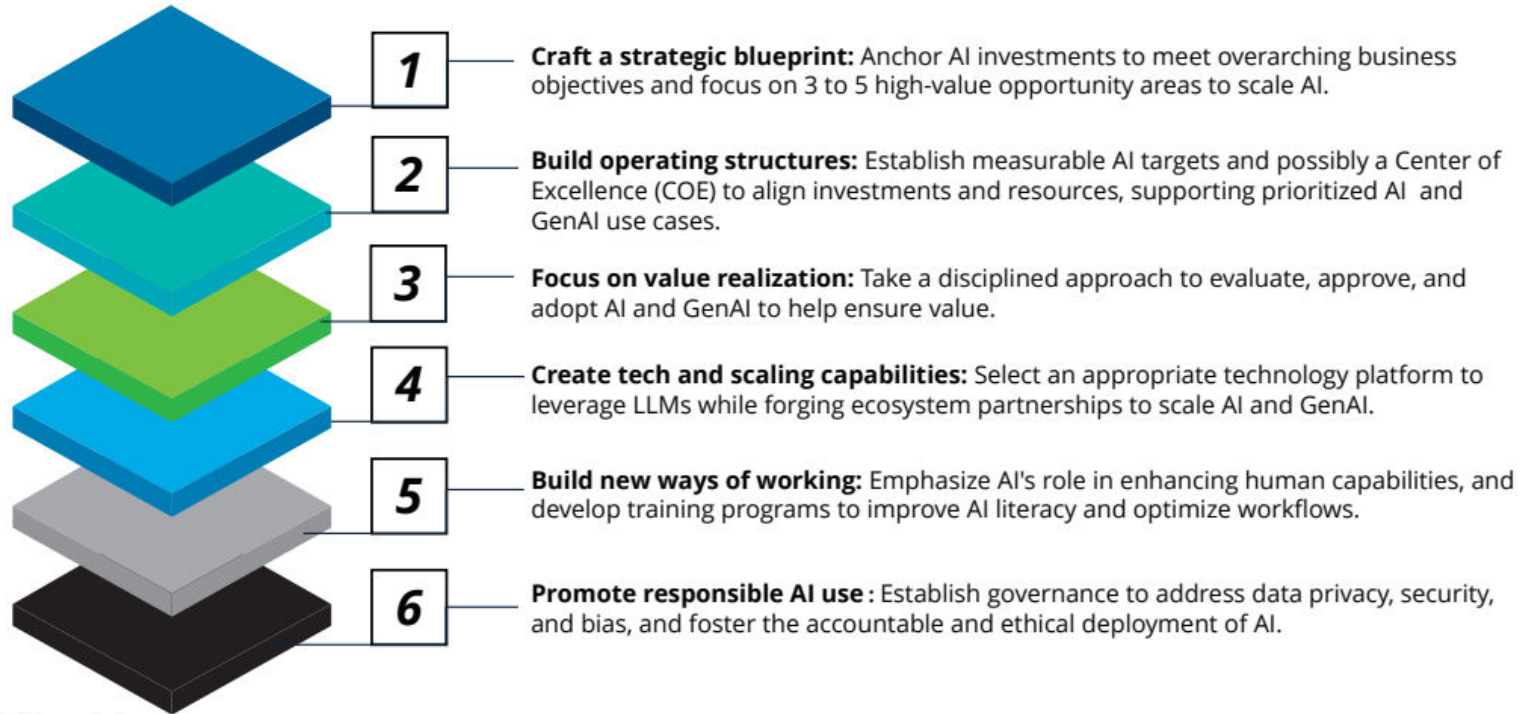


AI-generated training material



- AI translated operating procedures and technical documentation into virtual reality storyboards
- 10 training modules generated within 2 weeks

Companies need a comprehensive implementation strategy to benefit fully from AI in R&D



Source: Deloitte analysis

Conclusion



The use of AI in R&D is a significant opportunity to improve efficiency and quality of results



There is no ready-made playbook and no single tool chain



Many commercial offerings are just wrappers around the big LLMs and the vendor landscape will consolidate



Senior leaders need to engage



Med tech companies should choose a technology partner to enable proprietary models at acceptable cost



AI in R&D will not lead to a sustainable competitive advantage, once companies are through the adoption curve

Sources

- Deloitte: Is Generative AI changing the game for medtech, 2024
- Boston Consulting Group: AI Powered R&D, 2025
- Boston Consulting Group: Medtech's Generative AI Opportunity, 2025
- Arthur D Little: Eureka! On Steroids, 2025
- Accenture: Reinventing R&D in the age of AI, 2024
- M. Gindert and M.L. Muller, The Impact of Generative Artificial Intelligence on Ideation and the performance of Innovation Teams, 2024
- Zeiss: Can Microsoft GitHub Copilot Enhance the Productivity of Medical Software Development?, 2025
- TNO-ESI: Large Language Models for Systems Engineering, 2025

PHILIPS