



How **people & AI** **agents** build regulated products together.



Erez Kaminski
CEO & Founder



Many products are regulated

As technology complexity increases, so does the burden of compliance.

Healthcare



AI-driven diagnostics, surgical robots, remote patient monitoring and clinical trials, **drug development**.

Aerospace / Defense



Commercial aircraft, **autonomous drones**, control systems and other defense applications.

Automotive / Logistics



Cars, trucks and the systems that control them, including **autonomous driving** assistants

Other Industries

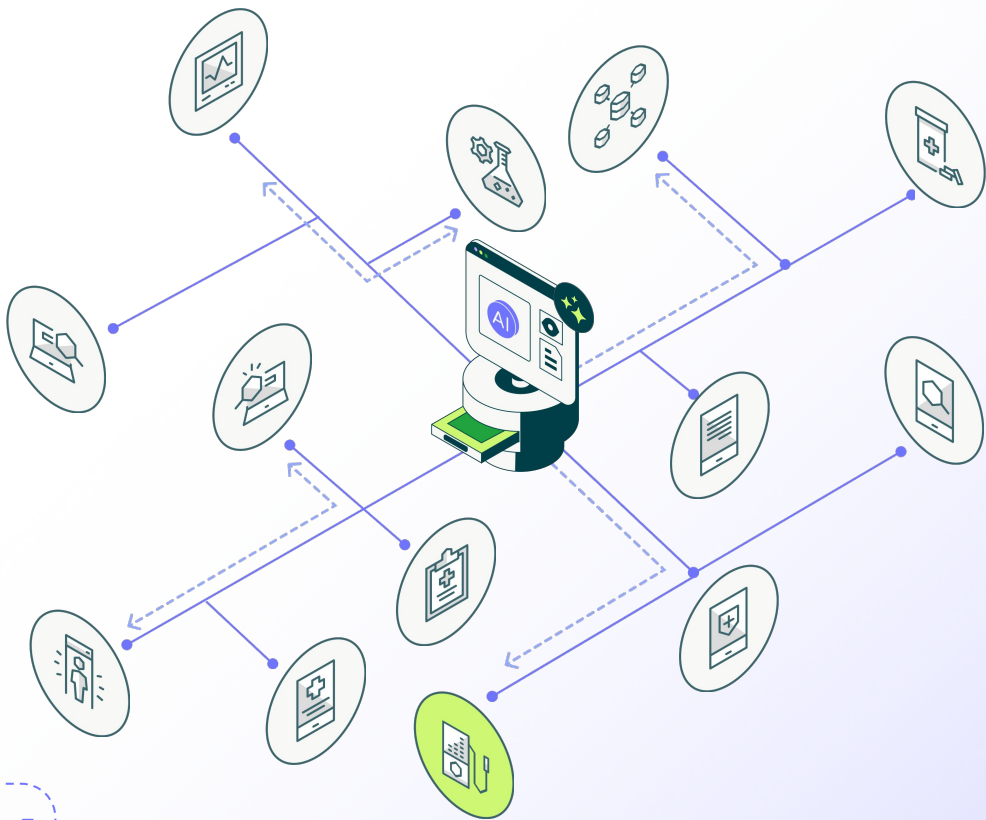


Energy, **Robotics**, Finance, Telecommunications, **Regulated AI**, and many others.



AI will only
amplify this
challenge

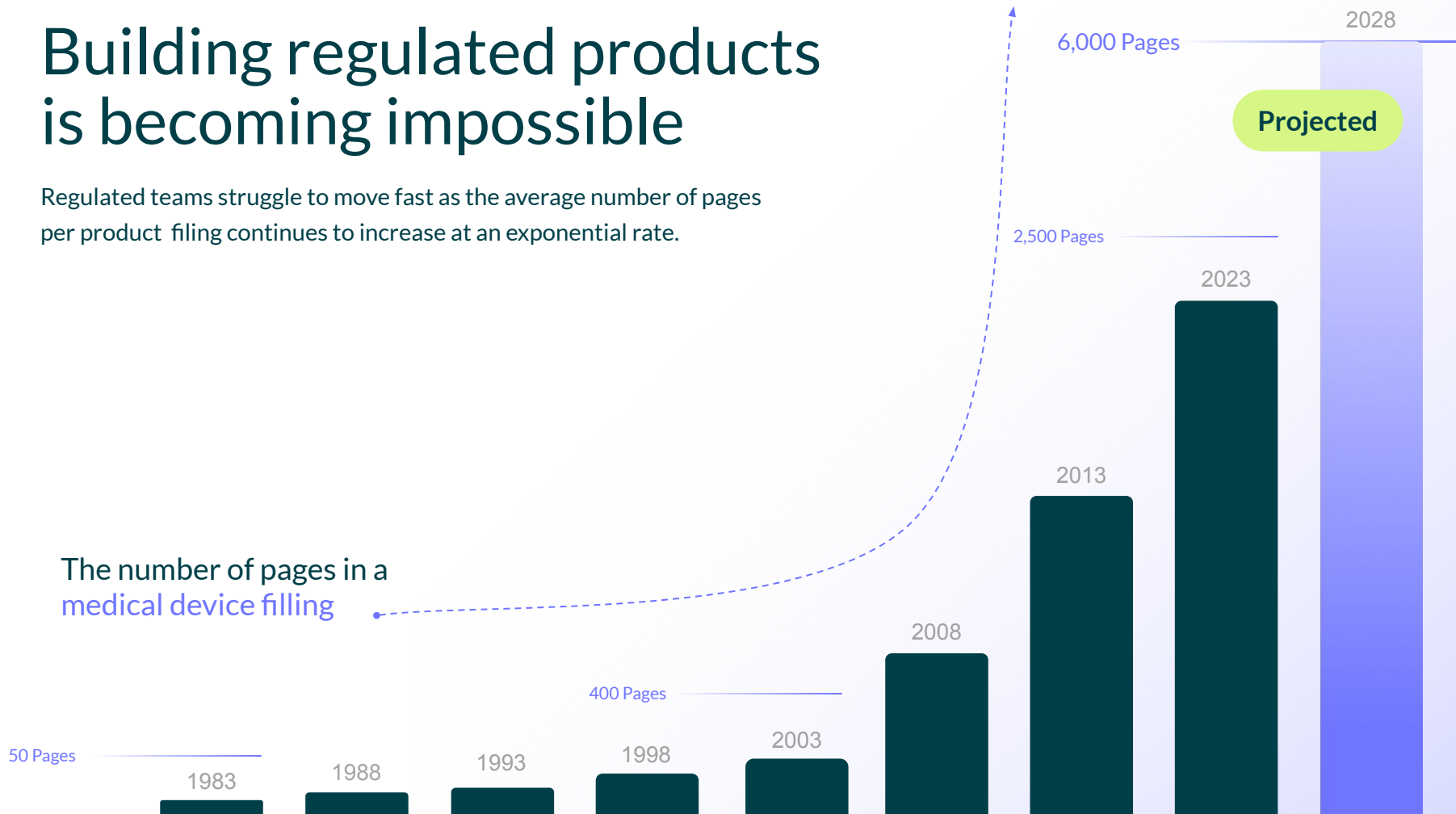
Systems are
becoming
more complex



Building regulated products is becoming impossible

Regulated teams struggle to move fast as the average number of pages per product filing continues to increase at an exponential rate.

The number of pages in a
medical device filing



Compliance is a massive Bottleneck

Stuck doing
paperwork

50-90%

of time is
documentation

Manual
processes
create costly
errors and
delays

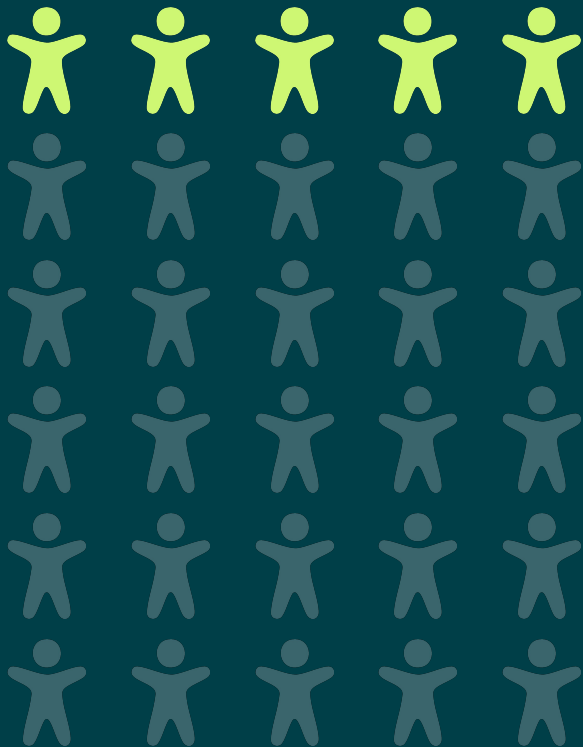
Can't ship products

10-1000

X

Slower product shipping





Today we have 100
people build the product,
and 500 document it.

This is not sustainable.

VP of R&D, Top 3 Life Science



01

02

Why Now

##

03

04

05

06

07

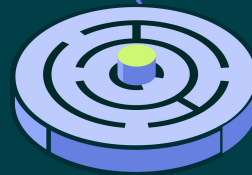
08

09

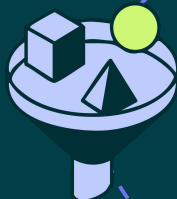
AI can finally **solve compliance** for regulated products



Global Regulations are an evolving **unstructured data** source with inconsistent formats and requirements



Product complexity is growing exponentially as modern systems become more software driven



Companies need to **follow a structured process** to ensure compliance with their procedures and regulations



Documentation is growing to a scale that makes it **impossible to manage**



AI can be used to generate **unstructured compliance data**



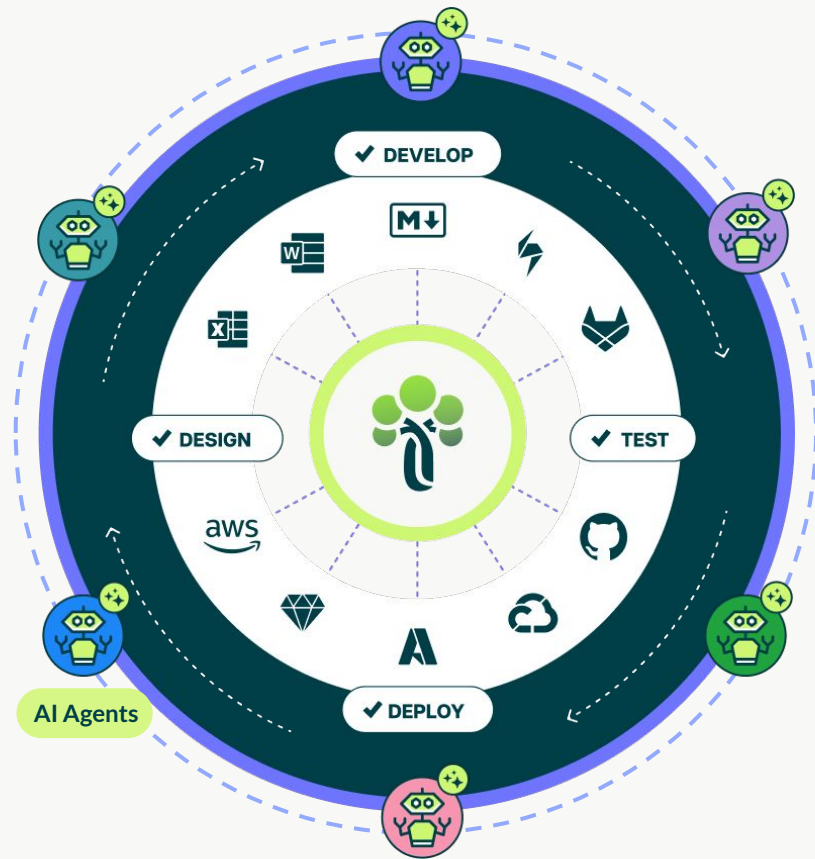
Regulators are now developing ways to use **AI to accelerate audits**



01
02
03 The Solution

04
05
06
07
08
09

Ketryx lets teams use Agentic AI to build regulated products 100x faster.



01

02

03

The Solution

#

04

05

06

07

08

09



Life science is our first vertical
where leaders already use
Ketryx to serve **25M patients**

Current Customers



Johnson&Johnson Medtronic

Meta



stryker

dexcom



inogen

enovis™



revvity

Growing **3.5x CARR**
in the last 12 months

\$3.5M

CARR

\$12M

NTM CARR Fcst

178%

NRR

7x

Revenue Growth
since Series A

\$83M

Full potential ARR

\$6M

TCV

Always-on AI Agent that accelerates safe innovation

Human-Agent Ecosystem

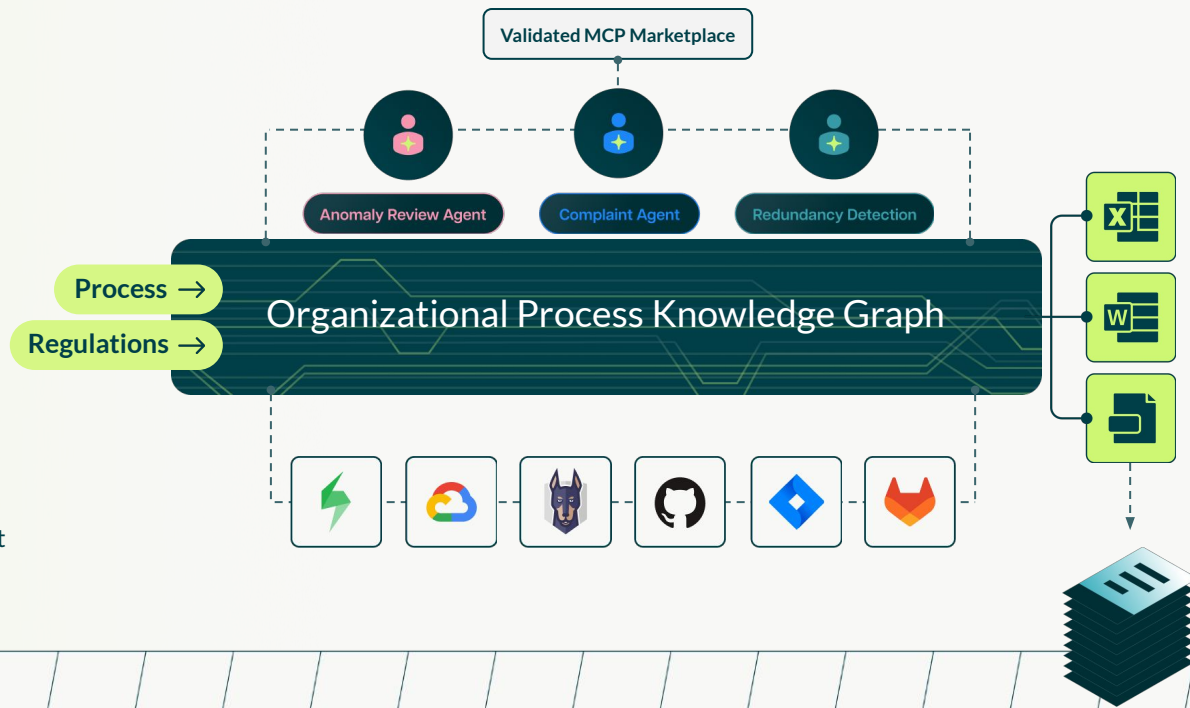
Control the workflows people and agents use to collaborate on products

Ensure process are followed

Learn organization graph and verify process are correctly executed

Complete database of record

Interoperate across IT systems to capture all product compliance information and record it



Ketryx: the Lifecycle Intelligence Platform



Johnson&Johnson

Medtronic

Meta

stryker

dexcom

The screenshot displays the Ketryx web application interface. The top navigation bar includes the Ketryx logo, a breadcrumb trail 'Ketryx / Real-time monitoring interface', and a 'Sync' button. A left sidebar contains a 'Back to projects' link and a list of navigation items: All Items, Releases, Design, Traceability, Graph, Risks, Risk controls, Verification and validation, Tests, and History. The main content area, titled 'All items', features a table with columns for Diff, Title, Type, Source, Tests, Approval state, and State. The table lists several items, including 'Dose Calculation Engine', 'Real-time Monitoring Interface...', 'Patient Profile Manager...', 'Infusion Rate Controller...', 'Drug Library Integration...', 'Alert Configuration System...', and 'Compatibility Verification Tool...'. Each row includes a checkbox, a status indicator (green plus, yellow SW, or red RC), and buttons for 'Open' or 'Closed'.

Diff	Title	Type	Source	Tests	Approval state	State
<input type="checkbox"/>	+ Dose Calculation Engine	RQ RC	SAMD-4	1	Approved	Closed
<input type="checkbox"/>	+ Real-time Monitoring Interface...	SW	SAMD-4	1	Pending 1/9	Open
<input type="checkbox"/>	⚙ Patient Profile Manager...	RQ	SAMD-4	1	Approved	Open
<input type="checkbox"/>	📦 Infusion Rate Controller...	SW	SAMD-4	1	Approved	Open
<input type="checkbox"/>	✖ Drug Library Integration...	SW	SAMD-4	1	Pending 1/9	Closed
<input type="checkbox"/>	Alert Configuration System...	SW	SAMD-4	1	Approved	Resolved
<input type="checkbox"/>	Compatibility Verification Tool...	RQ	SAMD-4	1	Pending 1/9	Resolved

Generate FDA-grade compliance reports in seconds, not months

04

Product

#

05

06

07

08

09



Upload files

Drop your documents, studies, and data files into Ketryx AI. Support for any format - PDFs, Word docs, spreadsheets, clinical data.



Generate & proof reports with Ketryx AI.

Our AI instantly analyzes content, extracts key information, identifies gaps, and creates publication-ready compliance documentation with complete source traceability.



Download compliant reports

Export professionally formatted reports ready for FDA, FAA, CE marking, and other global regulatory submissions.

The investigational drug ZB-3021, also known as ZONEPTINIB, is being evaluated for its efficacy and safety in treating adult patients with treatment-resistant depression (TRD). This Phase 3 clinical trial is a randomized, double-blind, placebo-controlled study designed to assess the drug's ability to reduce depressive symptoms in patients who have not responded adequately to at least two different classes of antidepressants. The study involves approximately 350 patients who will be randomized to receive either 50 mg or 75 mg of ZB-3021, or a placebo, over a 12-week treatment period, followed by a 2-week safety follow-up. The primary endpoint is the change from baseline in the Montgomery-Åsberg Depression Rating Scale (MADRS) total score at Week 8, with secondary endpoints including response and remission rates, as well as changes in functional impairment and quality of life. ¹

1 Low Confidence (23%) ⓘ

Review Recommended

Source 1 Document3.pdf

"A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of ZB-3021 in Adult Patients with Treatment-Resistant Depression"

Source 2 Document3.pdf

"Approximately 350 patients will be randomized in a 2:2:1 ratio to receive ZB-3021 50 mg, ZB-3021 75 mg, or placebo once daily for 12 weeks."

Source 3 Document3.pdf

"Primary Efficacy Endpoint: Change from baseline in Montgomery-Åsberg Depression Rating Scale (MADRS) total score at Week 8"

🗨️ ✎️ ✓ Accept

🔍 ⓘ

✕ 🗨️

Generate FDA-grade compliance reports in seconds, not months



Generate & proof compliant reports
with Ketryx AI.

The investigational drug ZB-3021, also known as ZONEPTINIB, is being evaluated for efficacy and safety in treating adult patients with treatment-resistant c... This Phase 3 clinical trial is a randomized, double-blind, placebo-controlled study designed to assess the drug's ability to reduce depressive symptoms in patients who did not respond adequately to at least two different classes of antidepressants. The study involves approximately 350 patients who will be randomized to receive 50 mg of ZB-3021, or a placebo, over a 12-week treatment period, followed by a safety follow-up. The primary endpoint is the change from baseline in the Montgomery-Åsberg Depression Rating Scale (MADRS) total score at Week 8, with secondary endpoints including response and remission rates, as well as changes in quality of life.

Low Confidence (23%) ⓘ
Review Recommended

Source 1 Document3.pdf

"A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of ZB-3021 in Adult Patients with Treatment-Resistant Depression"

Source 2 Document3.pdf

"Approximately 350 patients will be randomized in a 2:2:1 ratio to receive ZB-3021 50 mg, ZB-3021 75 mg, or placebo once daily for 12 weeks."



















Source 3 Document3.pdf

"Primary Efficacy Endpoint: Change from baseline in Montgomery-Åsberg Depression Rating Scale (MADRS) total score at Week 8"



Unlike competitors, Ketryx generates
documents the existing workflows.

Documents for this version

 SBoM - SOUP - Software Configuration Report Generated on 2022-10-13 10:20Z	  
 Cloud Configuration Report Generated on 2022-10-13 14:43Z	  
 Code Review Report Generated on 2022-10-13 14:53Z	  
 Risk Management File Generated on 2022-10-13 14:53Z	  
 System Requirements Specification Generated on 2022-10-13 14:53Z	  

Single Source of Truth for version release, risk management and compliance



Live tracking of progress across all connected systems



FDA-grade cybersecurity built-in

2.3 Release progress

Changes since 2.2.1

Items in this release: 1521

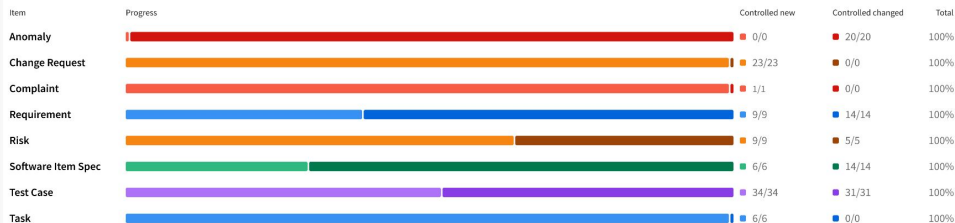
1420 Controlled 0 Uncontrolled 0 Unchecked 101 Deferred 178 New 63 Changed 22 Obsolete 1258 Unchanged

PROGRESS OF CONTROLLED ITEMS



New and changed design controls: 172

PROGRESS OF DESIGN CONTROLS



Show all uncontrolled items → Show all controlled items →

Changed vulnerabilities

5,101 vulnerabilities

UNKNOWN	LOW	MEDIUM	HIGH	CRITICAL	
843	83	3	254	500	
844 TOTAL	194 TOTAL	12 TOTAL	567 TOTAL	550 TOTAL	
Dependency		Declared in	Declared version		Vulnerabilities
WinUISuperComponents		/WinUI Client/Directory.Packages...	17.2.3		64 ▲
ActiveRecord		/webclient/Gemfile	<= 5.16.1		1,864 382 23 ▲
React		/config.json	@ 18.0.0		521
JavaScripts		/config.json	3.8.11 - 3.9.0		182 182 67

Transform Compliance with AI-Powered Automation

Contextual, fast AI Assistant and AI Agents to manage projects, detect issues and provide recommendations to maintain compliance.

Create a new requirement for cybersecurity, risks for that requirement, and risk controls for those risks

For your project, I would suggest the following 4 items:

- User Authentication and Access Control
- Sensitive Data Unauthorized Access to Implementation
- Multi-Factor Authentication
- Role-Based Access Control Enforcement

Should I continue?

The screenshot displays the Ketryx Requirement Conflict Detection Agent interface. The top bar includes the Ketryx logo and navigation icons. The main section is titled "Requirement Conflict Detection Agent" and features a "Run" button, "Edit" icon, and "Delete" icon. Below the title, there are tabs for "Findings and recommendations" (26) and "Agent settings". The "Findings and Recommendations" section shows a summary of the analysis: "The analysis of configuration item requirements has revealed significant conflicts primarily centered around user authentication, highlighting critical intersections between performance, regulatory compliance, and data handling. Specifically, the findings indicate that stringent security...". Below this, there is a table of findings and recommendations.

Findings and Recommendations	Rate this result
Findings and Recommendations	Rate this result
The analysis of configuration item requirements has revealed significant conflicts primarily centered around user authentication, highlighting critical intersections between performance, regulatory compliance, and data handling. Specifically, the findings indicate that stringent security...	
Show more	
Show all 26	Open 24
Applied 2	Dismissed 0
Search	
SAMD-4 Overlap in Data Management and Security Requirements	4 Findings
SAMD-8 Dashboard with predefined analytics	4 Findings
SAMD-3 Dose history	4 Findings
SAMD-1 Availability of at least 99.5%	4 Findings Applied 1 of 3
SAMD-8 Connect to Sensor	4 Findings Applied 1 of 3
SAMD-7 Cybersecurity	4 Findings Applied 1 of 3
SAMD-5 Design for dashboard GUI	4 Findings Applied 1 of 3
SAMD-9 Reliability	4 Findings Applied 1 of 3

Customers love Ketryx



"Ketryx has allowed us to **channel engineers' existing set of development, testing, and documentation practices directly into the generation of compliant documentation** with minimal additional burden."

Alex Chan
VP of Machine Learning, Beacon Biosignals



"Ketryx has significantly enhanced our operational efficiency by streamlining processes that previously **required manual duplication for Quality-related documentation...** This optimization has not only expedited the release process but also **delivered measurable value to both our Quality and Engineering teams.**"

Christy Hardin
Head of QMS Quality, RadNet/DeepHealth (NASDAQ: RDNT)



"Ketryx **supports our system of systems architecture really easily** out of the box. We were able to migrate our monolithic ecosystem into a single project and break it down into a desired state just within a couple of days. Ketryx delivered that because **it was designed to scale.** That was a huge plus."

Emre Gültürk
VP of Regulatory Affairs and Quality Systems, Heartflow



Ketryx Connector for Jira Reviews

The **Most** Experienced Team in Regulated AI

AI experts, healthcare veterans and regulators with a **proven track record of building AI tools** by hundreds of millions around the world.



Erez Kaminski

Founder/CEO (MS/MBA MIT)

Former Head of AI at Amgen.
Co-authored the global standard for medical AI risk management.

Jan Pöschko

Founder/CTO (MS UT Gratz)

Former CTO at Wolfram Cloud. Built AI systems powering Wolfram|Alpha and Mathematica.

Technology Leadership



A Team of Regulated Product Leaders

Leaders from regulated sectors—defense, aerospace, pharma, and MedTech—alongside the regulators who authored global standards for critical software compliance.

Compliance Leadership

Lightspeed

E¹⁴ UBIQUITY
VENTURES

Leading Enterprise SaaS Investors

A Cross-Industry Team of Innovators From:



AMGEN



Strategically located in Cambridge, MA

Medtech

BioTech

IT/Data

Defence

Energy



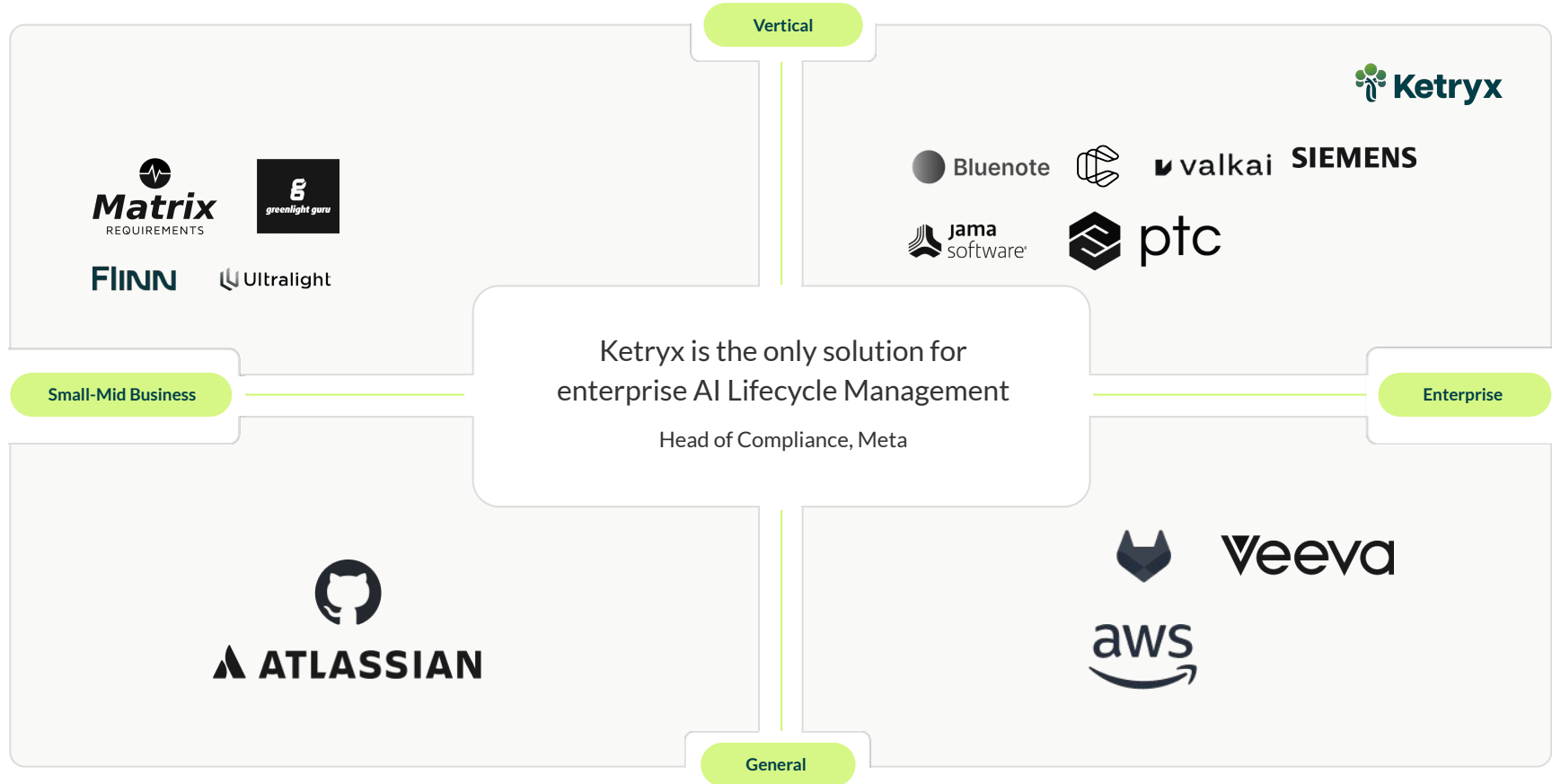
70%

F500 Life Science companies are steps away from Ketrix. We are uniquely positioned to convert proximity into pipeline-over \$1B of potential ARR

Agios
Aveo Pharmaceuticals
Takeda Pharmaceuticals
Partners Healthcare
Nucleus Scientific
Ariad
Broad Institute
Cambridge BioLabs
Abcam
TEVA Pharmaceuticals
H3 Biomedicine
CRISPR Therapeutics
Seres Therapeutics
Intellia
Boston Biomedical
Sanofi
Syros
Bio-Rad
Rubius
AbbVie
Aileron
Scholar Rock
Synlogic
RaNA Therapeutics
Novartis Institutes
Epizyme
J&J Innovation
Foundation Medicine
Bristol-Myers Squibb
Ipsen
Baxalta
Anylam
Editas Medicine
Momenta Pharmaceuticals
Saudi Aramco
Schlumberger
24M Technologies
Shell Techworks
Veolia
Twitter
Wistia
Atlas Venture
Draper Laboratory
edX
Cogo Labs
Highland Capital
Charles River Ventures
Facebook
Akamai
HubSpot
Intrepid
Philips
CIC
Apple
IBM
Amazon
Flagship Ventures
Intersystems
GlaxoSmithKline
Ragon Institute
Whitehead Institute
AstraZeneca Neuroscience
EMC
MassInnovation Labs
Amgen
Biogen
US DOT
FDA
Wolfarm
Microsoft
Oracle
Google
Shire
LabCentral
Pfizer
Department of Defense



Competitors



01

02

03

04

05

06

Competition

##

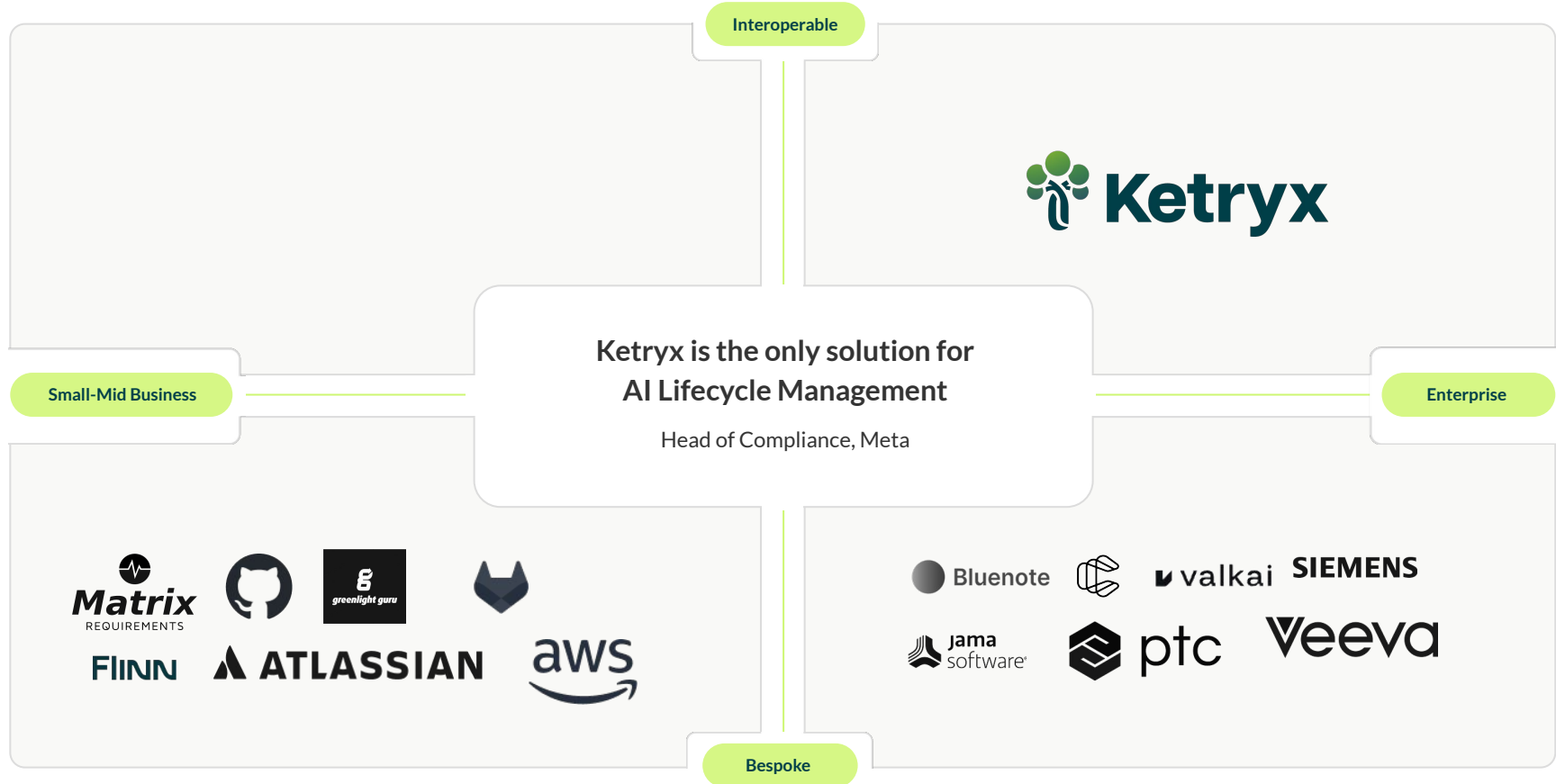
07

08

09



Competitors



01

02

03

04

05

06

07

08

09

10

11

12

13

14

15

16

17

Market Size

#

08

09

10

11



Our Market Opportunity in Regulated Industries

We expect our short
term market size to be:

~\$8.4B

\$60B

Connected MedTech

\$40B

Healthcare & Automotive

Automotive industry supports \$65B of
software and V&V services

>\$100B

Regulated Industries

Aerospace | Finance | Defense | Energy

Opportunity for Ketryx in the Med Device Industry:

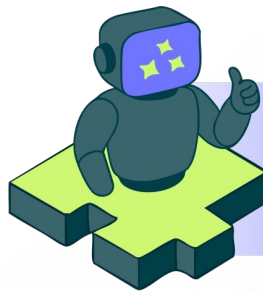
Potential ARR: \$4–4.5B

ALM Users | \$2–2.5B

400–500k seats (\$5k / seat) for SW
Engineering, Quality, and Product
* our highest seat price is \$10K

PLM Users | \$1.7–2B

700–800k seats (\$2.5k / seat) for HW
Engineering, Quality and Product



Regulated SW/AI

Medtech
\$500B

All Regulated Industries
Over \$10T

Opportunity for Ketryx in the Med Device Industry:

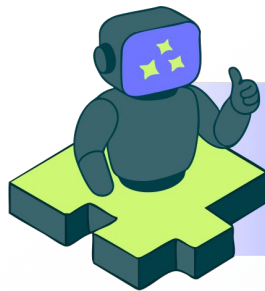
Potential ARR: \$4–4.5B

ALM Users | \$2–2.5B

400–500k seats (\$5k / seat) for SW
Engineering, Quality, and Product
* our highest seat price is \$10K

PLM Users | \$1.7–2B

700–800k seats (\$2.5k / seat) for HW
Engineering, Quality and Product



Regulated SW/AI

Hardware

Software

Medtech
\$500B

All Regulated Industries
Over \$10T

The Global Market for Regulated Products

Our Next Growth Engine

Future Industries

MedTech
\$500B

R&D

Engineering

Clinical Development

Manufacturing

Quality Assurance

Regulatory Affairs

Post-Market Surveillance

Market Size:

Pharma

\$1,600B

Healthcare IT

\$312B

Regulated AI

\$176B

Automotive

\$3,524B

Aerospace & Defense

\$3,524B

Energy & Utilities

\$3,524B

Finance

\$33,540B

Consumer electronics

\$33,540B


Heavy Industry



Telecommunications

Robotics

Maritime & Transport

Ketryx customers and active pipeline represent 37% of a \$500B MedTech Market

Our Customers		\$123B 24.6%	
	\$38B 7.6%	stryker	\$20B 4%
Medtronic	\$32B 6.4%	revvity	\$3B 0.6%
J&J MedTech	\$27B 5.4%	dexcom	\$3B 0.6%
\$186B 37%			

Pipeline		\$63B 12.6%	
	QuidelOrtho™	\$3B 0.6%	
	straumann	\$3B 0.6%	
	HOLOGIC™	\$4B 0.8%	
	SmithNephew	\$6B 1.2%	
	INTUITIVE SURGICAL™	\$8B 1.6%	
	Alcon	\$10B 2%	
	Boston Scientific	\$14B 2.8%	
	Baxter	\$15B 3%	

\$500B

01

02

03

04

05

06

07

08

09

Market Size

##

08

09

An accelerating commercial engine

Sales cycle is shrinking

85% reduction, 11 weeks FY25

Strong revenue growth

LTM 3.5x CARR, \$12M Fcst FY26

Growing customer base

46 customers, 10x since series A

**\$82M
Current
Potential
ARR**

\$8M

\$3.5M

Company	Current CARR	TCV	Use Case	Total Potential ARR
Dexcom	\$500K	\$1.36M	Diabetes	\$2M
Meta	\$435K	\$435K	Enterprise solution	\$15M
Revvity (Perkin Elmer)	\$300K	\$300K	Diagnostics	\$5M
RadNet	\$232K	\$327K	Radiology	\$2M
J&J	\$205K	\$587K	Surgical robotics	\$15M
Heartflow	\$195K	\$195K	Cardiology	\$2M
Stryker	\$180K	\$150K	Surgical robotics	\$5M
Inogen	\$160K	\$464K	Oxygen concentrator	\$1M
Roche	\$120K	\$120K	Diagnostics	\$15M
Medtronic	\$78.6K	\$170K	Diabetes	\$15M
Enovis	\$50K	\$50K	Orthopedic Care	\$1M
MedTech Growth (x15)*	\$655K	\$876K		\$2M
MedTech Startup (x20)	\$417K	\$414K		\$2M
Total	\$3.5M	\$5.5M		\$83M

01

02

03

04

05

06

07

08

09

Financials

##

09



An accelerating commercial engine

7 days

Fastest SMB Deal

90 days

Fastest Enterprise Deal

250%

Fcst YoY ARR growth

3.5x

LTM YoY Growth

\$12M

Fcst FY26 ARR

46

Customers & growing

6x

Enterprise Logo Growth
From Series A

10x

Logo Growth
From Series A

**\$82M
Current
Potential
ARR**

\$8M

\$3.5M

Company	Initial Deal Size (ARR)	Current CARR	TCV	Near term Projected ARR	Use Case	Total Potential ARR
Dexcom	\$350K	\$500K	\$1.36M	\$1M	Diabetes and AI	\$2M
Meta	\$318K	\$435K	\$435K	\$1M	Enterprise solution for medtech	\$15M
Revvity (Perkin Elmer)	\$120K	\$300K	\$300K	\$1M	Diagnostics and AI	\$5M
RadNet	\$100K	\$232K	\$375K	\$0.5M	AI for radiology	\$2M
J&J	\$192K	\$205K	\$769K	\$0.75M	Autonomous surgical robotics	\$15M
Heartflow	\$120K	\$195K	\$195K	\$0.3M	AI for cardiology	\$2M
Stryker	\$150K	\$180K	\$150K	\$0.5M	Surgical robotics	\$5M
Roche	\$120K	\$120K	\$120K	\$0.5M	Diagnostics and AI	\$15M
Medtronic	\$30K	\$78.6K	\$200K	\$0.5M	Diabetes and AI	\$15M
Enovis	\$50K	\$50K	\$50K	\$0.25M	Orthopedic Care	\$1M
MedTech Growth (x11)*	\$385K	\$495K	\$495K	\$0.6M		\$2M
MedTech Startup (x24)	\$542K	\$580K	\$580K	\$0.75M		\$2M
Total		\$3.5M	\$5M	\$8M		\$82M

01

02

03

04

05

06

07

08

Financials

##

09



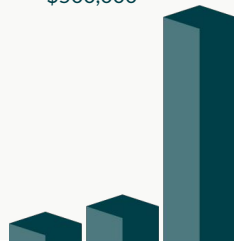
Our largest customers consistently expand

This represents 35% of FY2026 ARR Goal

Medtronic

**\$0 to \$79,000
in 18 months**

Land	\$30,000
Expand	\$79,000
Potential N12M	\$500,000



revvity

**\$0 to \$300,000
in 7 months**

Land	\$120,00
Expand	\$300,000
Potential N12M	\$1,000,000



∞ Meta

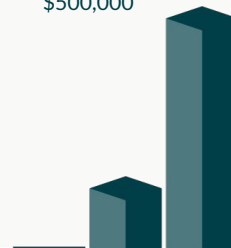
**\$0 to \$435,000
in 5 months**

Land	\$258,000
Expand	\$435,000
Potential N12M	\$1,000,000



**\$0 to \$120,000
in 6 months**

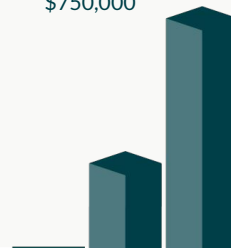
Land	\$100,000
Expand	\$232,000
Potential N12M	\$500,000



Johnson&Johnson

**\$0 to \$586,000
in 6 months**

Land	\$182,000
Expand	\$586,500
Potential N12M	\$750,000



Additional capital can help us
accelerate to \$10M. In FY26
Q1, we surpassed that plan.

Our customers represent
25% of the global
MedTech revenue



01

02

03

04

05

06

07

08

09

Financials

##

01

02

03

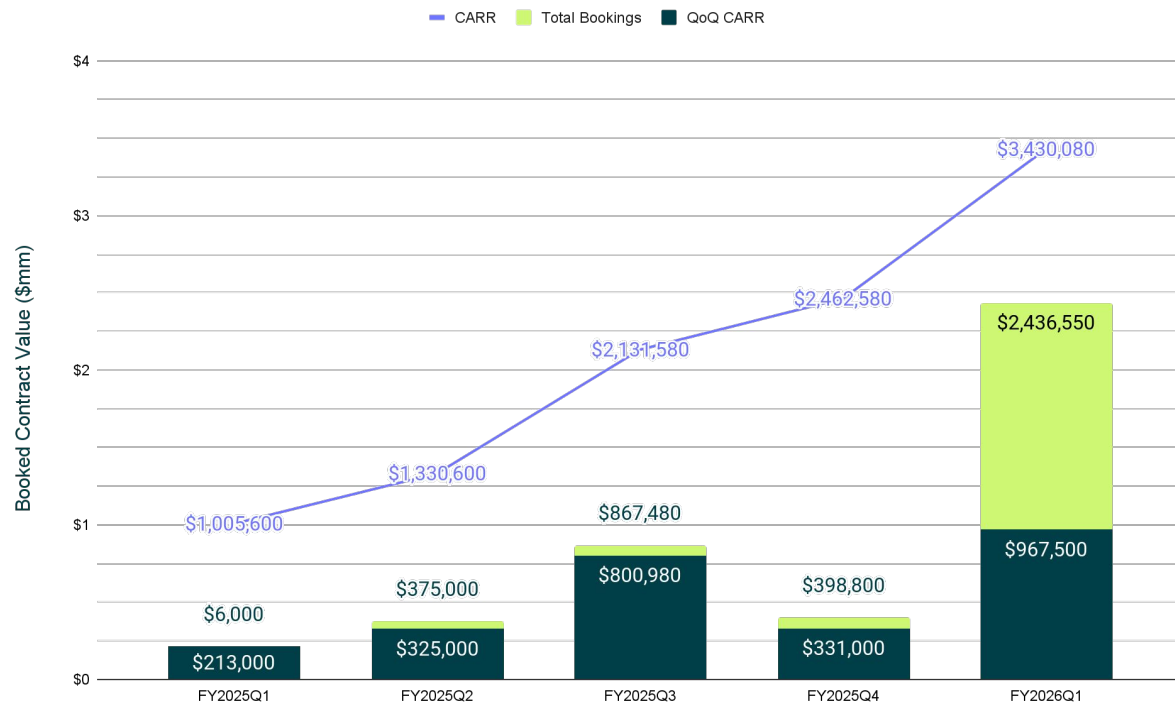
04

05

06

CARR Growth with Total Contract Booking

Accelerating
ability to extract
budget from
customers



Raising \$30M

Accelerate in our beachhead market and expand to adjacent industries.

Milestones



Accelerate build out
of AI Agent ecosystem



New industry
Move to adjacent markets



Grow team from 60 to 120:

- R&D and Product
- Sales and Marketing
- Implementation

Goals

\$20M ARR

In the next 18 months

20 global MedTech and Pharma

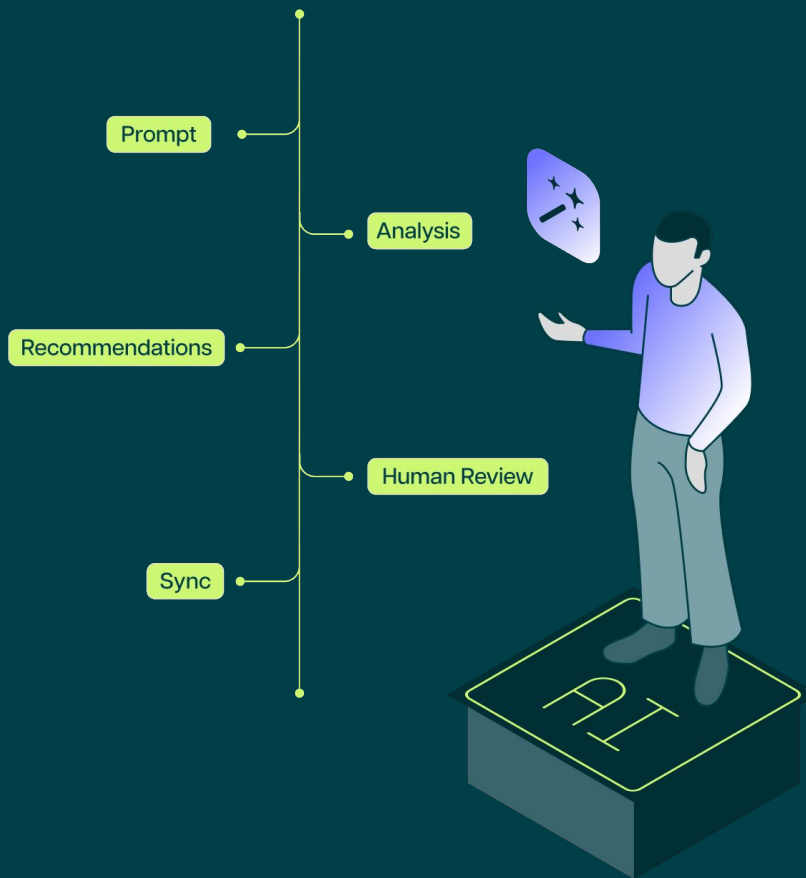
Companies use Ketryx

10 global brands

From automotive or defense use Ketryx



Join us in making systems safe and reliable.



Erez Kaminski
CEO & Founder

✉ erez@ketryx.com

in [@erezkaminski](#)



