RegKey

Drug Development Costs $3B and Takes 10 Years.

RegKey Creates $800M+ in value and Saves 1–2 Years Per Drug.

regkey.ai arunad@Regkey.ai

Regulatory Success Is the Key

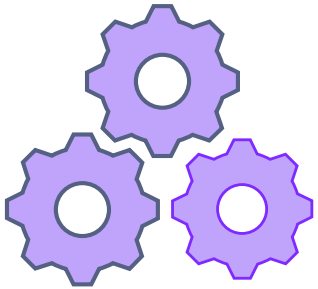


Every Week Delay Costs $3M

One regulatory error can wipe out years and billions

Amplifies Human Experts Using Curated AI

Creates $800M+ Value Per Drug



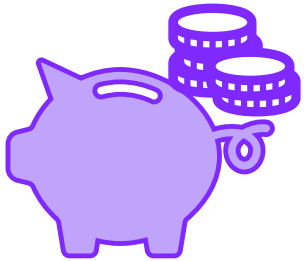
10X Efficiency Gain

One scientist
tenfold output



1-2 Years Faster to Market

Regulatory work
4–5 months
Done in 5 days



$800M+ More Savings

10X Faster.
10X Cheaper.
Per Drug

RegKey

Born from Experience

Built to Break Barriers

Team of Experts from Pharma,
Biotech, AI/ML experts
and Business Leaders



Aruna Dontabhaktuni, PhD

Co-Founder CEO
30 Years in Pharma



Somdip Datta, PhD

Co-Founder CTO
25 years in Tech



Dolly Parasrampuria,PhD
Regulatory Strategy
30 years of experience



Gangadhar Vakkalagadda, PhD
Regulatory Affairs
30 Years in Pharma



Partha Nandy, PhD
Clinical Pharmacology
30 years of experience



Lee Kosmac
Business Adviser
40 years in investment

Real Results. Growing Demand

- 8 Paying Clients

- 15 Clients in Active Discussion

A game-changer. RegKey improved our efficiency by 90%



Dr. Giridhar Tirucherai
Vice President
ScholarRock

Agentic AI + Human Experts

Accelerate Preparation. Ensure Confident Submissions



Curated AI

Trained pharma data
zero hallucination



Guided

50+ expert 1500+
years of experience



Secured

Enterprise-grade
security full protection



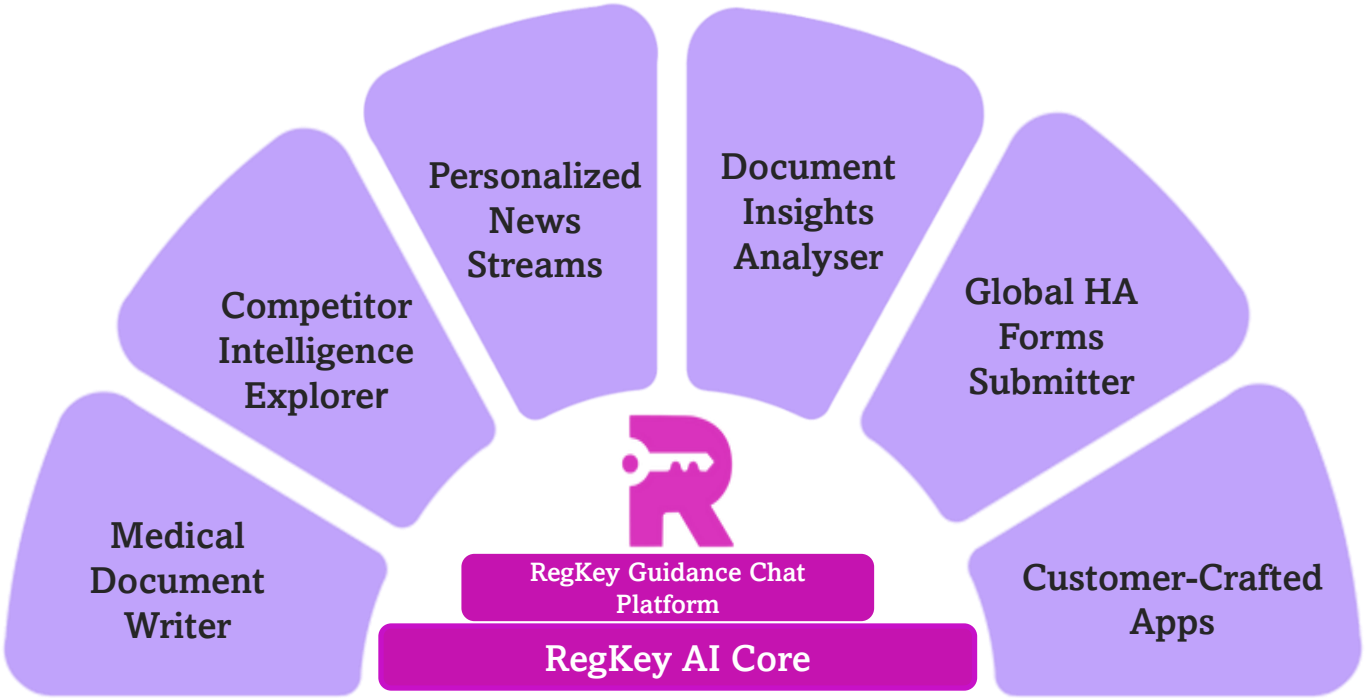
Customized

Integrates with client's
workflows & systems

RegKey

RegKey Platform

For All Regulatory Tasks, Powered by Curated Data, Continuous Learning



Access to Domain Experts for 1:1 Meetings

Glimpse of Experts Powering RegKey

Clinical Pharmacology



Christopher Banfield, PhD
Clinical Pharmacology
30 years of experience



Aruna Dontabhaktuni, PhD
Founder & CEO
30 years of experience



Michael Stevens, PharmD
Head of Business Dev
30 years of experience

Pharmacometrics



Serge Guzy, PhD
Head of Pharmacometrics
35 years of experience



Nathan Teuscher, PhD
Pharmacometrics Lead
25 years of experience



Liang Zhao, PhD
Pharmacometrics Lead
30 years of experience
15 Years in FDA

Regulatory Affairs



Ed Patten, MS
Regulatory Affairs
30 years of experience
15 Years in FDA



Joel Goldstein, MS
CMC Regulatory Affairs
30 years of experience



Suresh Mallikaarjun, PhD
Clinical Pharmacology
35 years of experience
5 Years in FDA

Impact: $400K Investment →

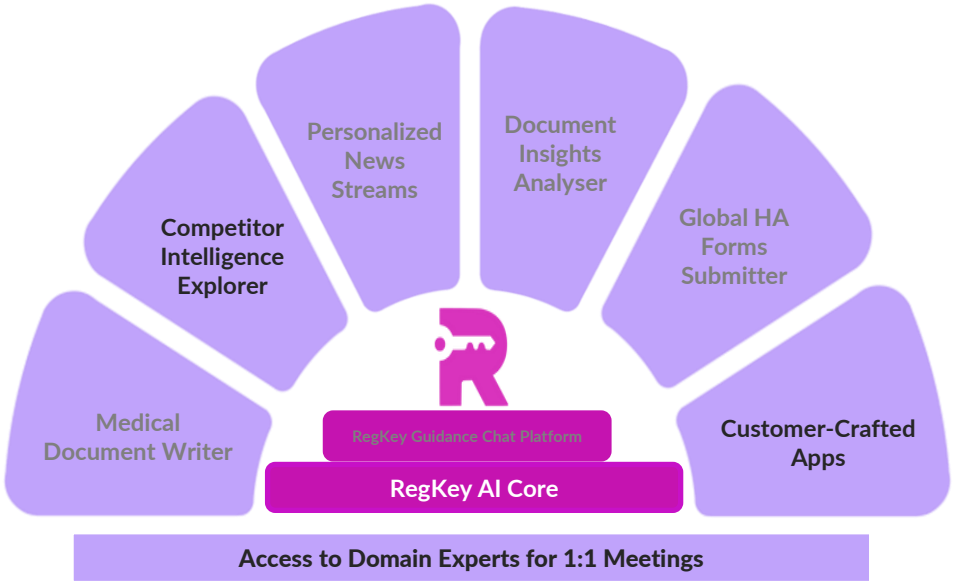
$2B Acquisition

Boston based Biotech in early Phase 2 - needed differentiation

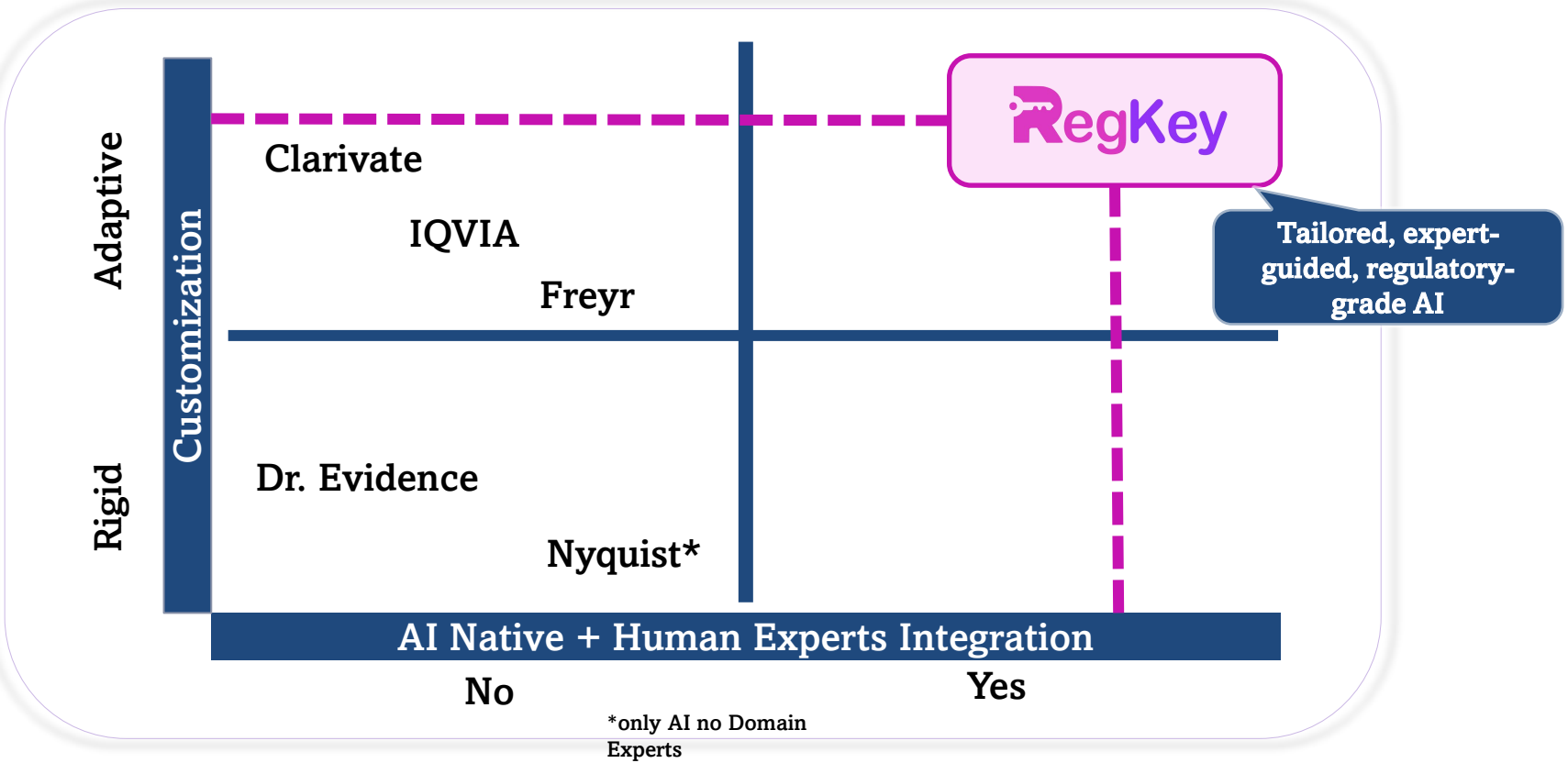
RegKey Competitor Intelligence: Rivals dosed daily or weekly.

AI insight + **Expert interpretation** = winning strategy

Outcome: **$2B** Acquisition by end of Phase 2



Only AI + Human Expert Platform



RegKey

Regulatory + Medical Writing $14B Market, 15% YoY Growth

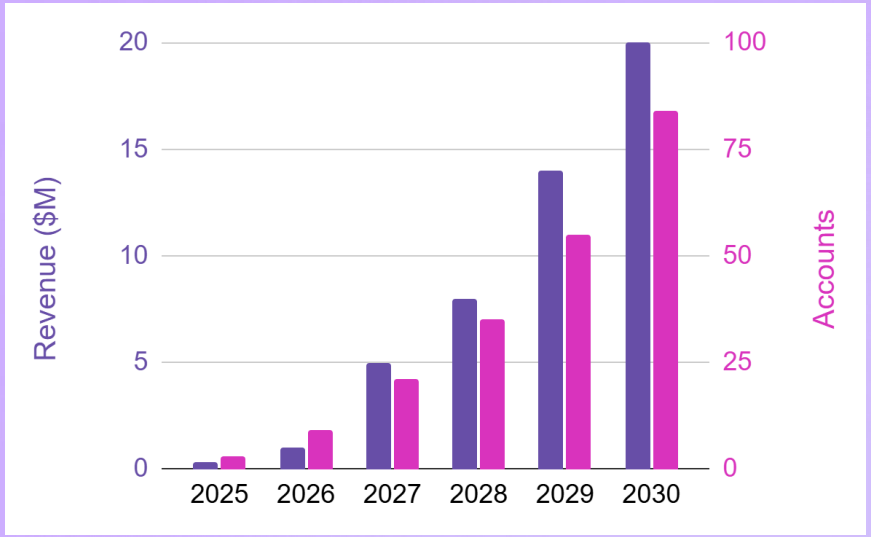
RegKey Revenue

- **SaaS Subscription (ARR)**
- **Tailored Expert Advisory**

Company Size	Subscription/year
Small (4000)	$100K +
Medium* (1000)	$200K +
Large (45)	$500K +

***ICP – Head of Regulatory at the Firm with Drugs in Phase 2 or 3**

Conservative ARR Projection $5M in 2 yrs and $20M in 5 yrs



***ICP – Total Medium Size Companies ~ 5000**

RegKey

Milestones Achieved & ASK







Qualified Angel investors get 40% return from NJEDA

10M



FDA Guidance

Competitor Intelligence

AI Writer

Deployment Plan







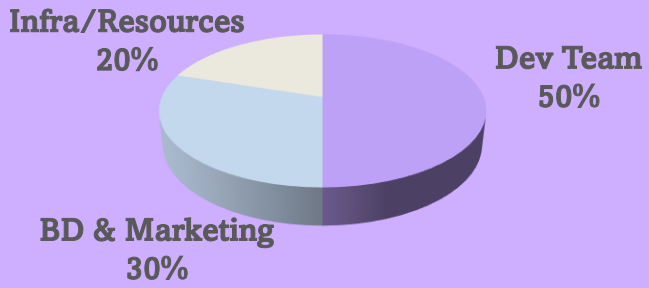


Expand Team

BD & Marketing

Medical Devices

EMA Guidance



RegKey

RegKey

Helps Hundreds of Life-Saving Medicines Reach Patients Fast

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