ArcaScience

Seek less, discover better

The First Regulatory-approved Benefit-Risk Intelligence platform

From Proven Collaboration to Enterprise-Scale Evidence Infrastructure

ARCASCIENCE | APRIL 2026 | CONFIDENTIAL

Meeting's agenda

Chapter	Topic
1	Summary
2	Proven Results
3	Validated Performance
4	Architecture
5	Regulatory Compliance
6	Scientific Evidence
7	Maximizing ROI
8	Compliance
9	Solution Positioning
10	Business Model
11	Impact & testimonials

CHAPTER 1: SUMMARY

ArcaScience is improving medicines success with the first dynamic, comprehensive & prospective Benefit-risk platform

ArcaScience
Seek less, discover be

Company Overview

24

Specialized Language Models

in an 8-stage pipeline

100B+

Data Points

Benefit-risk database

$10M

Capital Raised

with $7M in Sep 2025

Track Record

10+

Regulatory Submissions

accepted using our products (FDA, EMA, PMDA)

Compliance

GAMP 5 | ISO 27001 | SOC 2 | 21 CFR PART 11 | HIPAA | GDPR | HDS | ALCOA+

CHAPTER 1: SUMMARY

Your One-Stop Shop for Benefit-Risk Intelligence

Across the Entire Drug Development Life Cycle

PERFORMANCE & TRACEABILITY

92%

AE extraction F1

97%

Benefit coverage

100%

Source-linked outputs

10+

Accepted submissions

+25pp

vs. general LLMs

GAMP 5 · ISO 27001 · SOC 2 · 21 CFR Part 11

SAVINGS

€500K+

Saved per drug cycle

92%

Cost reduction vs. CRO

€2,5K

/month starting price

From 1.2M CRO cost to affordable platform pricing

TRIAL DESIGN

100B+

Data points screened

3x

More DDIs detected

5–7yr

Earlier B/R anticipation

Optimize designs with the largest B/R evidence base

CHAPTER 2: PROVEN RESULTS

+5% Drug Approval Rate

Thanks to **earlier predictive and comprehensive** risk minimization & mitigation strategies, late-stage termination costs are avoided, leading to a **significant increase in regulatory approval rates.**

[AstraZeneca,2025; ICM, 2024 ; JMAI 2025]

CHAPTER 2: PROVEN RESULTS

-60% Benefit-risk Evaluation Cycle Time

Across DSURs, PSURs, PBRER, & unnecessary amendments, labor hour savings alone **exceed the annual investment**

[Sanofi,2025; ICON, 2025]

ArcaScience × Blue Chip Pharma 1 : Added value on Hidradenitis Suppurativa

Already delivered. Results that proved extensive data capabilities.



The Project

ArcaScience produced structured benefit-risk reports (sBR) for a biologic in Phase 2 development for HS, covering:

- **250million** datapoints screened, over a 20-year span
- **Dynamic comparators** against marketed standard of care (clinical + RWD)
- **-60%** benefit-risk evaluation time with all outputs structured to BRAT and FDA frameworks
- **Public and private** data dynamically integrated

Validated Against Scientific Standards

Capability	Performance	Validation Method
Biomarker extraction	F1 = 90.05%	Internal gold standard
Biomarker coverage (top 30)	92%	External (Disgenet)
Risk extraction	F1 = 92.1%	Internal gold standard
Risk data coverage	96%	Sanofi external validation
Benefit extraction	F1 = 92%	Internal gold standard
Benefit data coverage	97%	Sanofi external validation

CHAPTER 3: VALIDATED PERFORMANCE

Operational Comparison: Manual/CRO vs. ArcaScience

Time to Deliverable	**Cost**
Manual/CRO: ~3–6 months VS ArcaScience: **~1 to 2 weeks**	Manual/CRO: ~$500k–$1.2M VS ArcaScience: **starts at $2,5k/month**
Evidence Sources	**FDA/EMA/AI Compliance**
Manual/CRO: Baseline set VS ArcaScience: **Integrative baseline - any sources**	Manual/CRO: N/A VS ArcaScience: **Fully aligned**

Benefits extraction coverage reached 95% at engagement: an area of active improvement. Risk extraction and biomarker coverage exceeded expectations.

Five Auditable Stages. Full Traceability.



Data Retrieval

Data Harmonization

Data Storage

Knowledge Update

Extended Analysis

Across all five stages, 24 task-specific Small Language Models (SLMs) handle extraction, normalization, and classification, trained on diverse types of evidence. All findings are standardized to MedDRA, specialized ontologies, ensuring full traceability from output to the source.

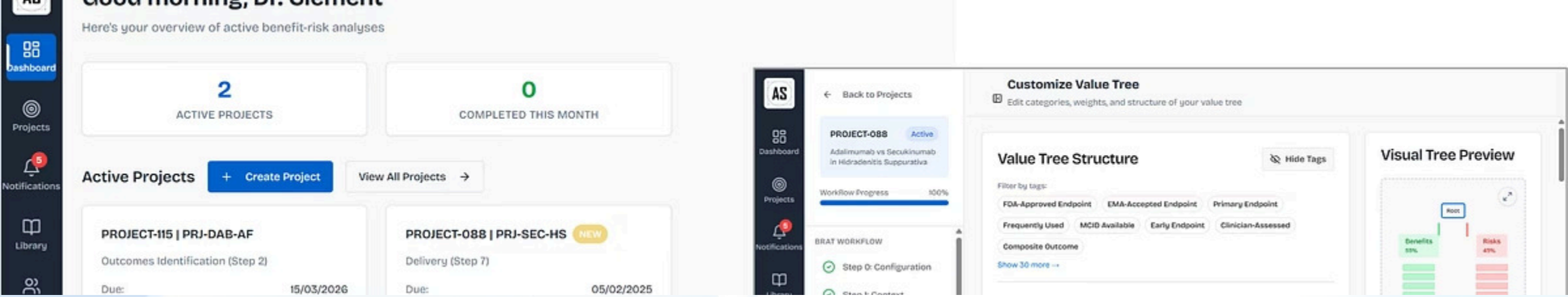
Outputs Aligned to Regulatory Deliverables

BRAD/SBRA	eCTD / Clinical Overview	PBRER
Analysis of Condition	2.5.6.1 Therapeutic context	-
Current Treatment Options	2.5.6.1 Therapeutic context	-
Benefits	2.5.6.2 Benefits	18.2 Benefits
Risks	2.5.6.3 Risks	18.2 Risks
Risk Management	2.5.6.3 Risks	Add to conclusion section
Benefit-Risk Assessment	2.6.0.4 Benefit-Risk Assessment	18.2
Conclusion	2.5.0.4 Benefit-Risk Assessment	18.2
Clinical Landscape + Efficacy	Global synthesis of clinical activities, sponsors, treatments	eCTD 2.5.4 / PBRER 16
Adverse Events Report	Synthesis of all AEs related to drug and standard of care	eCTD 2.5.6.3 / PBRER 18.2
Benefit-Risk Summary	Tailored synthesis of the full benefit-risk analysis	eCTD 2.5.6 / submission-ready BRAD

Every output maps to eCTD Module 2.5 and PBRER sections, reducing assembly burden between internal analysis and submission-ready documentation.

Peer-Reviewed Performance. Published Results.

Capability	Performance	Benchmark	Verified Publication
AE extraction precision	Macro-F1 0.92	Purpose-built vs. general-purpose	Chen S. et al., 2023 - NLP to Automatically Extract the Presence and Severity of Esophagitis in Notes of Patients Undergoing Radiotherapy. JCO Clinical Cancer Informatics. + Li, Chen et al., 2024 - AE-GPT: Using Large Language Models to Extract Adverse Events from Surveillance Reports. PLoS ONE, 2024. Fine-tuned GPT-3.5 vs. BERT/BioBERT on VAERS data.
NLP AE extraction F1	F1 = 0.94	Lenient micro-F1 on n2c2 2018	Mahendran & McInnes, 2021 - Extracting Adverse Drug Events from Clinical Notes. AMIA Joint Summits Transl. Sci. Proc. + Rodriguez-Esteban R. et al., 2022 - Challenges and Opportunities for Mining Adverse Drug Reactions. Database, Volume 2022, baac071.
Regulatory / BRA authoring time	Up to 60% reduction	vs. manual process	McKinsey & Merck, 2024 - Rewiring Pharma's Regulatory Submissions with AI and Zero-Based Design. McKinsey + Kim JH & Song YK, 2024 - Utilizing Temporal Pattern of Adverse Event Reports to Identify Potential Late-Onset Adverse Events. Expert Opinion on Drug Safety, Vol. 23, No. 9, pp. 1183–1190.
PSUR/DSUR authoring time	Up to 60% reduction	vs. manual process	Alpha Life Sciences, 2024 - Safety Squared: Accelerating DSUR and PSUR Creation Through AI-Powered Automation. + Luo Y, Thompson WK et al., 2017 - Natural Language Processing for EHR-Based Pharmacovigilance: A Structured Review. Drug Safety, Vol. 40, No. 11, pp. 1075–1089.



CHAPTER 8: THE MISSION

The First Prospective Integrated & dynamic Benefit-Risk Evaluation solution

Auditable

Every conclusion traceable to its source evidence. No black boxes. No "trust-me" moments.

Prospective

Built at each phase. The insights arrives when it can still change the outcome.

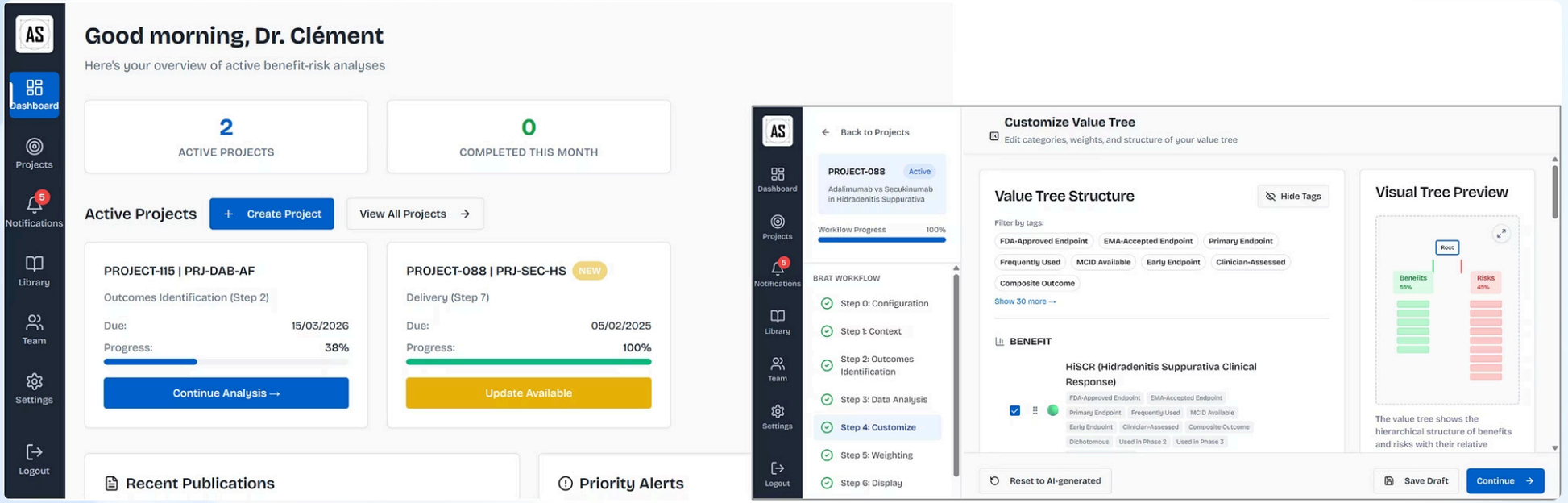
Integrated

Benefit and risk evaluated together, not apart.

ArcaScience – Seek less, discover better

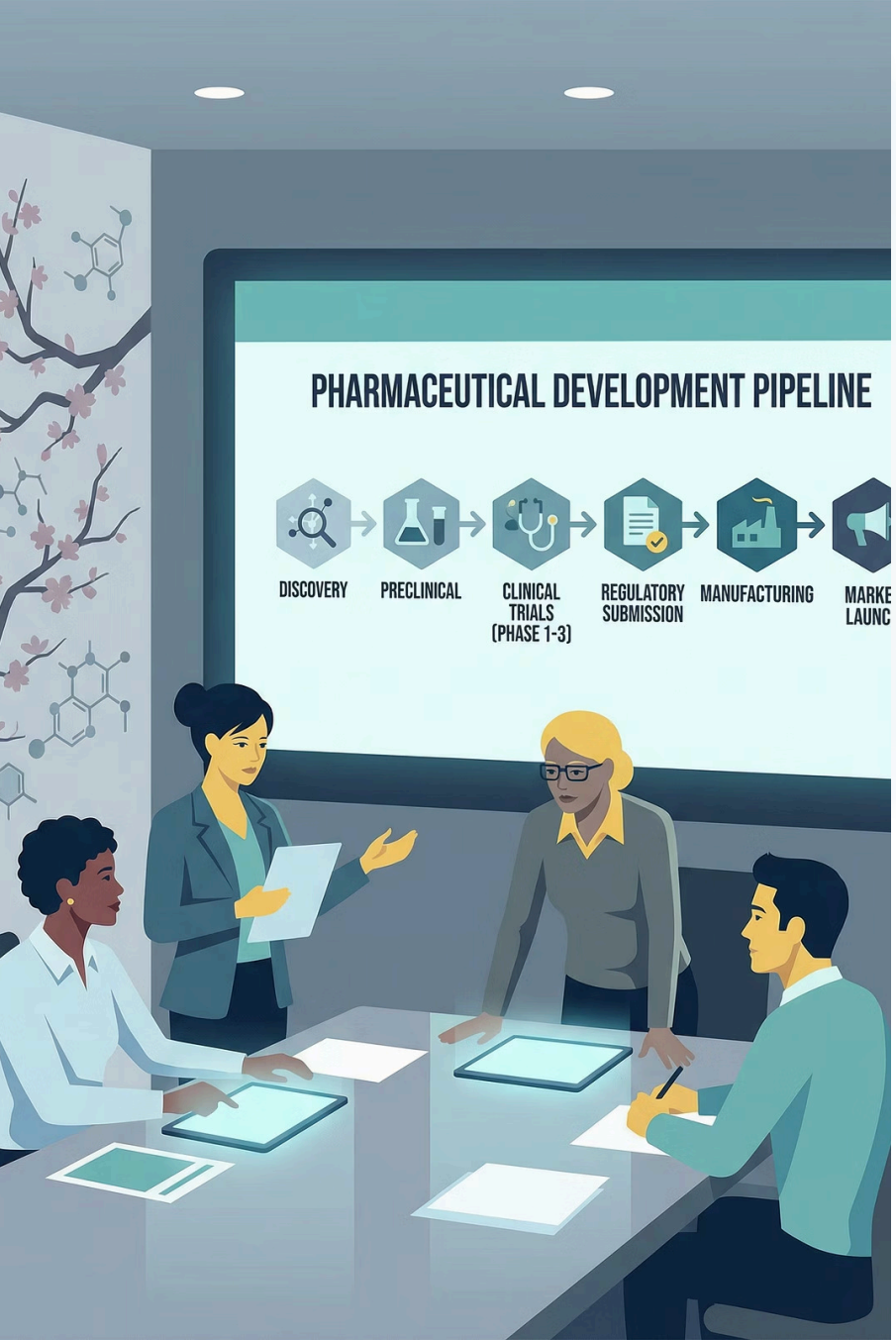
Inspired by : Working group XII Guideline E2C (R2)

The First Prospective Integrated & dynamic Benefit-Risk Evaluation solution



The demo:

- 100 billion datapoints, over a 50-year span with comparator highlighting
- Comparison against marketed standard of care (clinical + RWD)
- All outputs structured to BRAT and FDA frameworks
- Data dynamically integrated



CHAPTER 6: EXAMPLE OF A CLIENT'S PIPELINE

ArcaScience Mapped to Client's Assets

Specific assets. Prepared added value.

CHAPTER 6: CLIENT'S PIPELINE

Asset	Phase	BRA Challenge	ArcaScience Value
Tolebrutinib	Post-CRL	Favorable B/R could not be established: DILI signal, fatal case, liver transplant	Evidence reframing for resubmission; subpopulation analysis; identification of patient segments with favorable B/R
Dupixent	Multi-Ph3 / Marketed	9 indications, COPD population shift, peak EUR 22B target	Continuous B/R updates across indications; COPD-specific safety profiling; consistency checking
Amlitelimab	Phase 3	Novel anti-OX40L; KS signal in Ph2; comparator B/R vs. Dupixent	Mechanism-specific safety evidence structuring; differentiation B/R framework
Rilzabrutinib	Multiple Ph3	Hematology / rare disease; cross-indication complexity	Cross-program safety signal detection; indication-specific B/R

Tolebrutinib

FDA CRL asks for evidence reframing. ArcaScience structures the analytical case for resubmission.

Dupixent COPD

9 indications and growing. COPD introduces ~300,000 US adults with fundamentally different comorbidity and polypharmacy profiles.

Amlitelimab Ph3

As the potential next-generation immunology asset, its BRA positioning relative to Dupixent is critical. Phase 3 BRA needs to be built for durable regulatory differentiation.

Every Stage Where Benefit-Risk Decisions Matter



Preclinical / Translational

- Mechanism-aware safety reasoning from preclinical data
- Signals interpretation across species and models
- Biomarker identification for clinical monitoring



Clinical Development

- Evidence structuring for go/no-go phase transition decisions
- Subgroup identification for adaptive trial design
- Real-time evidence refresh as new trial data emerges



Pharmacovigilance

- Risk Evaluation complementing case processing
- Safety Surveillance
- PSUR benefit and risk sections automation



Benefit-Risk / Submission

- CIOMS XII / Structured BRA aligned
- Updateable BRA over time (not static documents)
- Will pre-populate BRAD, eCTD 2.5 and PBRER sections

Specialized Infrastructure Outperforms Build or Buy

Why Not Use GPT-5 or Enterprise LLMs?

Dimension	General LLMs	ArcaScience
AE extraction precision	67%	**92%**
Output format	Prose text	Structured, source-linked
Hallucination risk	Non-zero	**Zero**
Auditability	Opaque	Per-step auditable
Regulatory compliance	Not GxP-designed	GAMP 5 Cat. 5
Traceability	None	Full chain

For regulatory-grade evidence structuring, domain-specific models outperform by 25 percentage points.

CHAPTER 10 : BUSINESS MODEL

Flexible pricing: no reason not to work together

Choose the financial model that best aligns with your strategic objectives and usage patterns.

Key Metric	Option A (Success)	Option B (Monthly)
Annual Base Cost	€2,500/month ~~vs €250,000+/year *industry standard*~~	€6,250 ~~vs €20,000/month *industry standard*~~
Success Fee Exposure	€80,000 per approved asset	None
Lock-in Period	Annual (license renewal)	None (monthly opt-out)
Best For	Cost-conscious start, pay on success	High-usage teams wanting flexibility
Compliancy Service	1 Regulatory consultant FOR FREE ~~instead of ~€150.000/year~~	1 Regulatory consultant FOR FREE ~~instead of ~€150.000/year~~

Flexible Opt-Out

You may discontinue the monthly subscription at the end of any calendar month with 30 days' written notice. This offers no penalty and no lock-in commitment.

Option B : Full Platform Access

Full, unrestricted access to all screening and development workflows. No success fee applies.

Switch Mechanism

Unilateral election allows you to switch from Option A to Option B at any time. Upon switch, annual license fees cease, and any accrued but untriggered success fee obligations are canceled. The switch is irrevocable for the remainder of the current contract year.



CHAPTER 10: BUSINESS MODEL

Our Commitment: We Succeed When You Succeed

ArcaScience is more than a vendor; we are a dedicated regulatory evidence partner, deeply invested in your success.

For this reason, we provide a Project Lead, **free of charge**, to boost your usage of the platform and reduce attrition even more.

Aligned Interests

Our success fee model ensures our goals are intrinsically linked to your drug approvals and milestone achievements.

Dedicated Partnership

An ArcaScience project lead acts as an extension of your team, providing proactive support and strategic guidance with regulators.

Regulatory Acumen

Benefit from our established relationships with global regulatory bodies (FDA, EMA, PMDA) and accepted platform outputs.

CHAPTER 11: IMPACT & TESTIMONIALS

Testimonials : The Impact of Full Regulatory Alignment

> We observed +5% approval rate when B/R and Risk Mitigation strategy is fully aligned with regulatory authority recommendations.
>
> *Christophe Cans, Sanofi's Innovation Lead*

> 20% of drug candidates fail due to poor understanding of the safety landscape. ArcaScience eliminates this risk.
>
> *Stephane Rouault, Roche Head of Innovation, ArgenX Clinical Lead*

Thank you !

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