



Setting the Scene Phil Reason, CEO

Instem Information Solutions For Life

Capital Markets Day July 2021



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Instem Capital Markets Day

Position and Mission

A leading provider of IT solutions & services to the life sciences market

Enabling our clients to bring life enhancing products to market faster





New Group Overview

We help clients collect, analyse, report and submit data to regulatory agencies with confidence and to reveal new insights from public and proprietary data.

Study Management Solutions

Software that empower organizations to more efficiently collect, review, manage and report Discovery and Preclinical data

Regulatory Solutions

Software, outsourced services and consultancy for managing, storing, sharing, submitting and maintaining information compliant with FDA, EMA and other agency regulations

In Silico Solutions

Enabling researchers to generate new scientific insights through the identification, extraction and analysis of actionable information

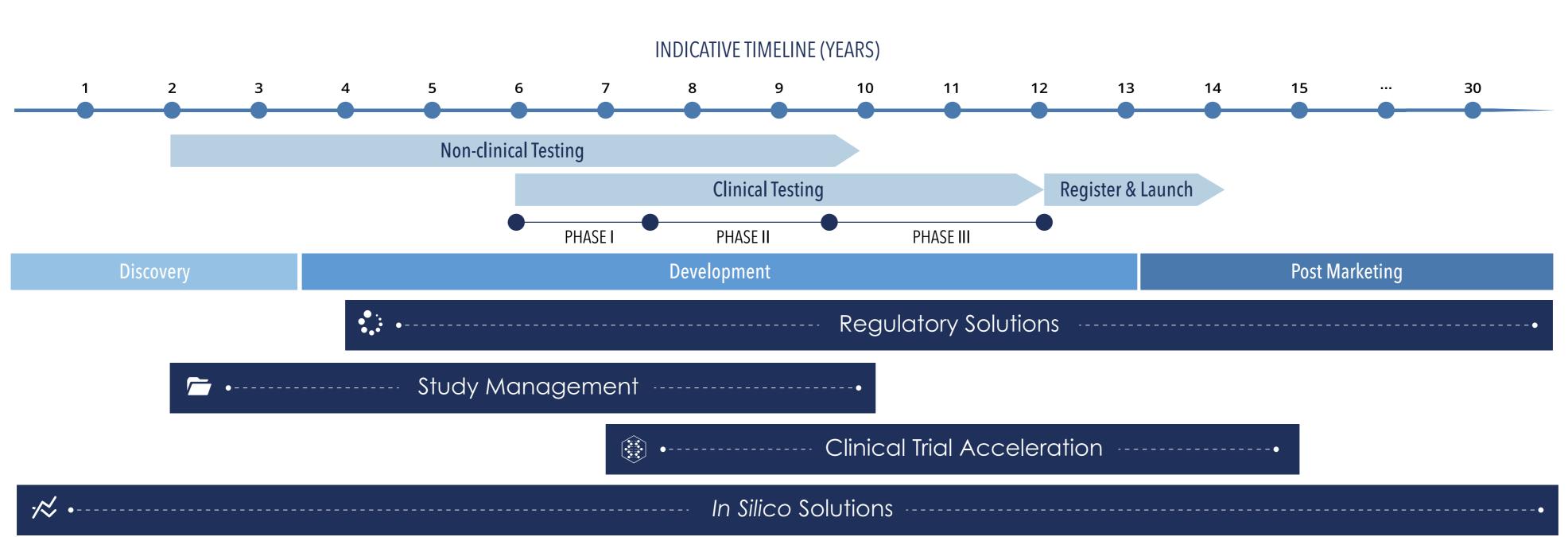
Clinical Trial Acceleration Solutions

Technology solutions and consulting services to facilitate data integration, statistics, analytics and insights for companies of any size or stage of clinical trial analysis





Instem Solutions from Discovery to Post-Marketing



- It takes ~13 years and costs \$2.56Bn to bring a drug from patent registration to marketing approval
- Revenue loss the year after drug patent expiry is frequently >50%
- 1 day earlier to market adds >\$2m patent protected revenue for a • >\$750m / year revenue drug

Improving R&D efficiency creates significant value for our clients



Growth Strategy

- next 3-5 years
- Scalable platform in place investment made; highly leverageable
- Three distinct and deliverable opportunities to drive further growth:

1. Organic revenue growth

- Further market penetration
- Cross-selling
- AI-enabled KnowledgeScan & Leadscope
- New products / services

2. Margin improvement

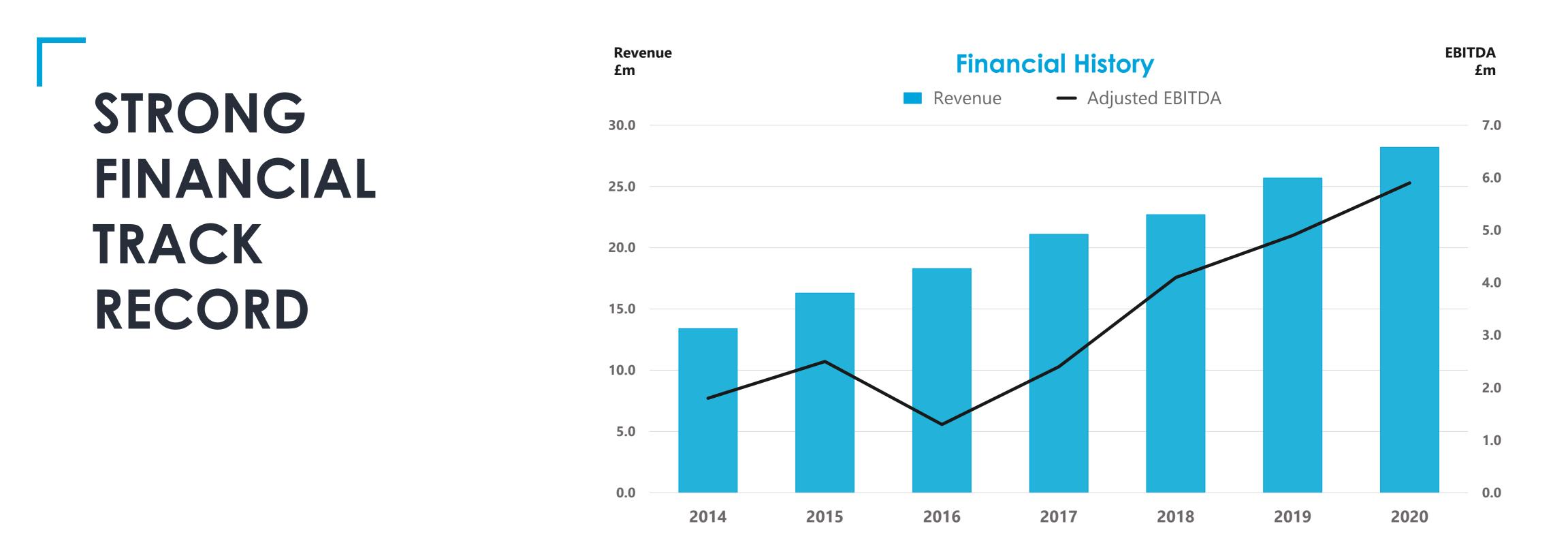
- Aiming for industry leading EBITDA margins – near term target 25%+
- Conversion to SaaS deployment
- More extensively leveraging global infrastructure

Management targeting revenue of £100-150m (previously £50-75m) organically / inorganically over

3. Accretive M&A

- Penetration in existing markets
- Entry into adjacent markets
- Strategic partnerships a potential stepping-stone





	£m	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019	FY2020	CAGR	Pro Forma 2020 ¹
Revenue		13.4	16.3	18.3	21.1	22.7	25.7	28.2	11%	c.49.0
Revenue Growth			22%	12%	15%	8%	13%	10%		
Adjusted EBITDA		1.8	2.5	1.3	2.4	4.1	4.9	5.9	18%	c.10.0

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1. Estimated pro forma unaudited revenues and adjusted EBITDA for Instem + The Edge + dwise in the 12 months ended 31 December 2020





Growth of Software-as-a-Service

- Enhanced client experience latest versions, enhanced support, lower total cost of ownership, scalability,
- Higher quality of Instem earnings financial smoothing, future revenue visibility, c.40% uplift
- Able to more rapidly deploy additional modules
- Opportunity for new products and services
- Simplifies logistics to help clients with their aspiration of data integration, sharing and exploitation
- c.20% of existing users transitioned to SaaS, others aware of end of 2023 deadline
- >70% of new clients SaaS from day 1





M&A Funding, Objectives and Criteria



- Consolidate a highly fragmented software supplier market
- Facilitate a huge reduction in the cost/time of life sciences R&D
- Create new market leading positions
- Generate cross-selling
 opportunities
- Margin Expansion through economies of scale

Funding through

- Equity fundraises most recently £15m July 2020
- Operational cash generation
- Issue of equity
- Modest debt if needed (none currently)

Criteria / History

- Acquisitions expected to be earnings accretive in first full year
- Target minimum ROCE 10% (pre-synergies) growing to 15%+
- 8 acquisitions in 10 years post-IPO







INTEGRATION Phil Ledsome Product Director



Integration

predict late-stage failures

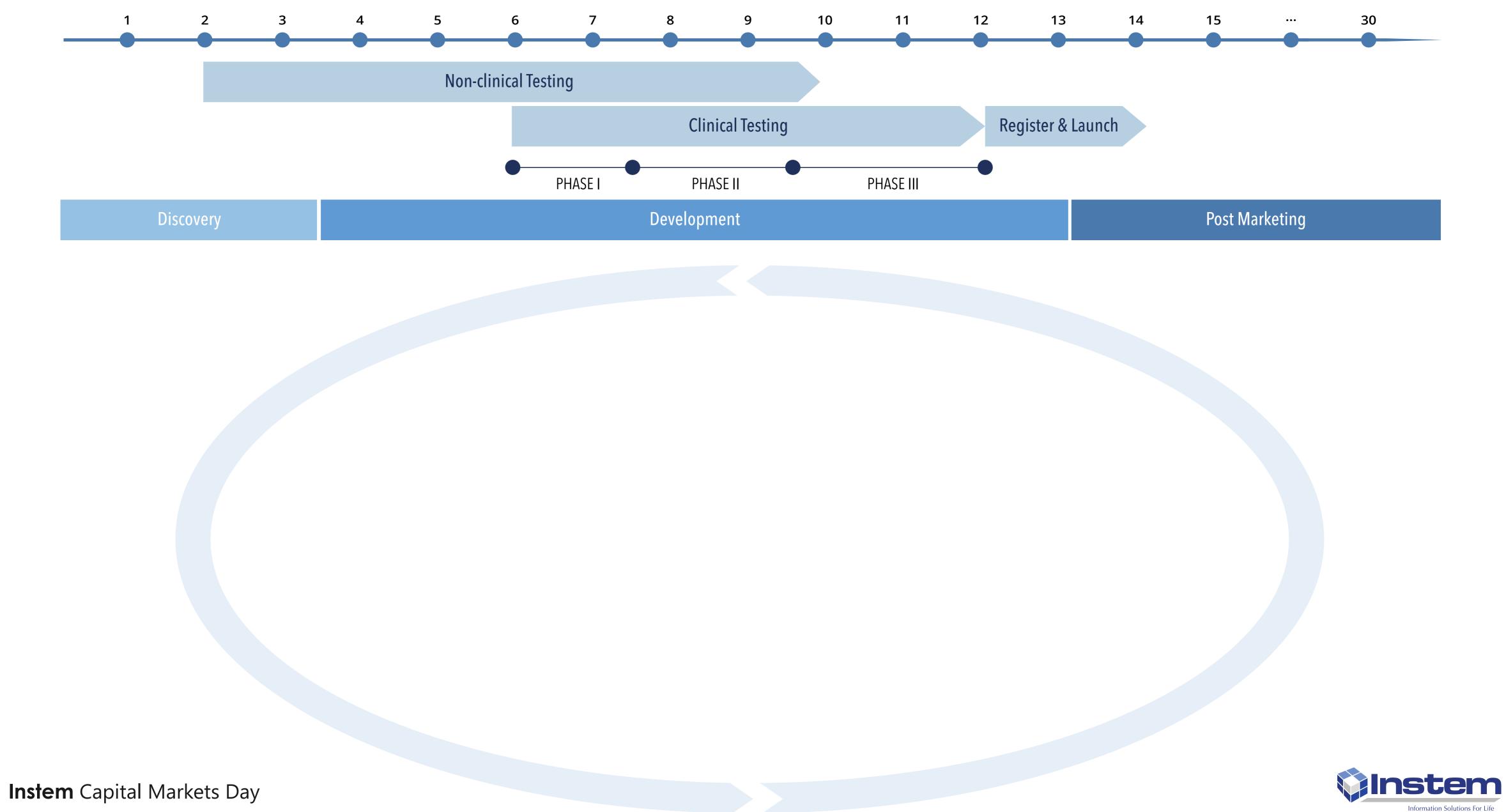
The solution is to learn from the successes and failures contained within pre-clinical and clinical study data to make better informed R&D safety decisions

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The pharmaceutical R&D process is long and expensive because of the difficulty to

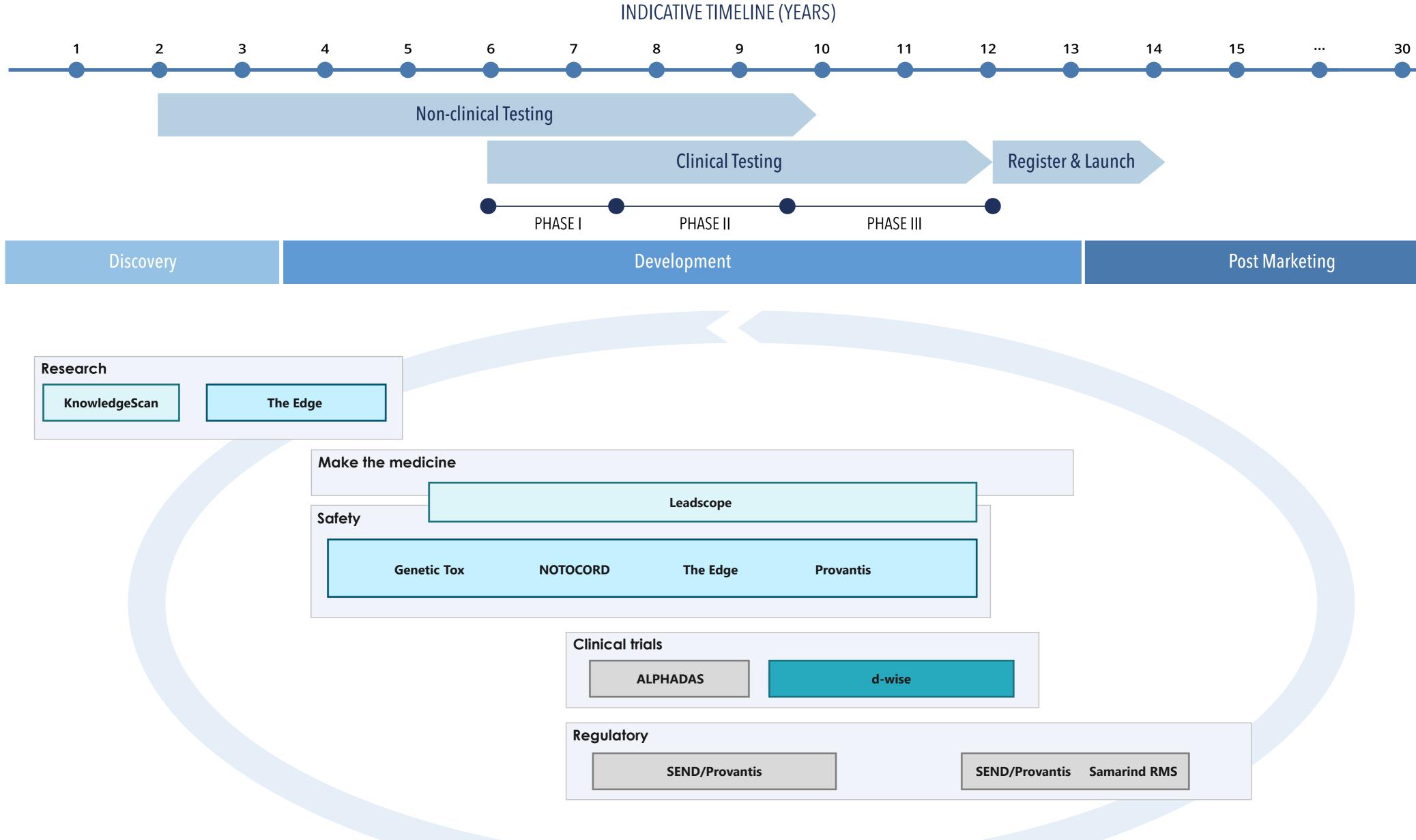






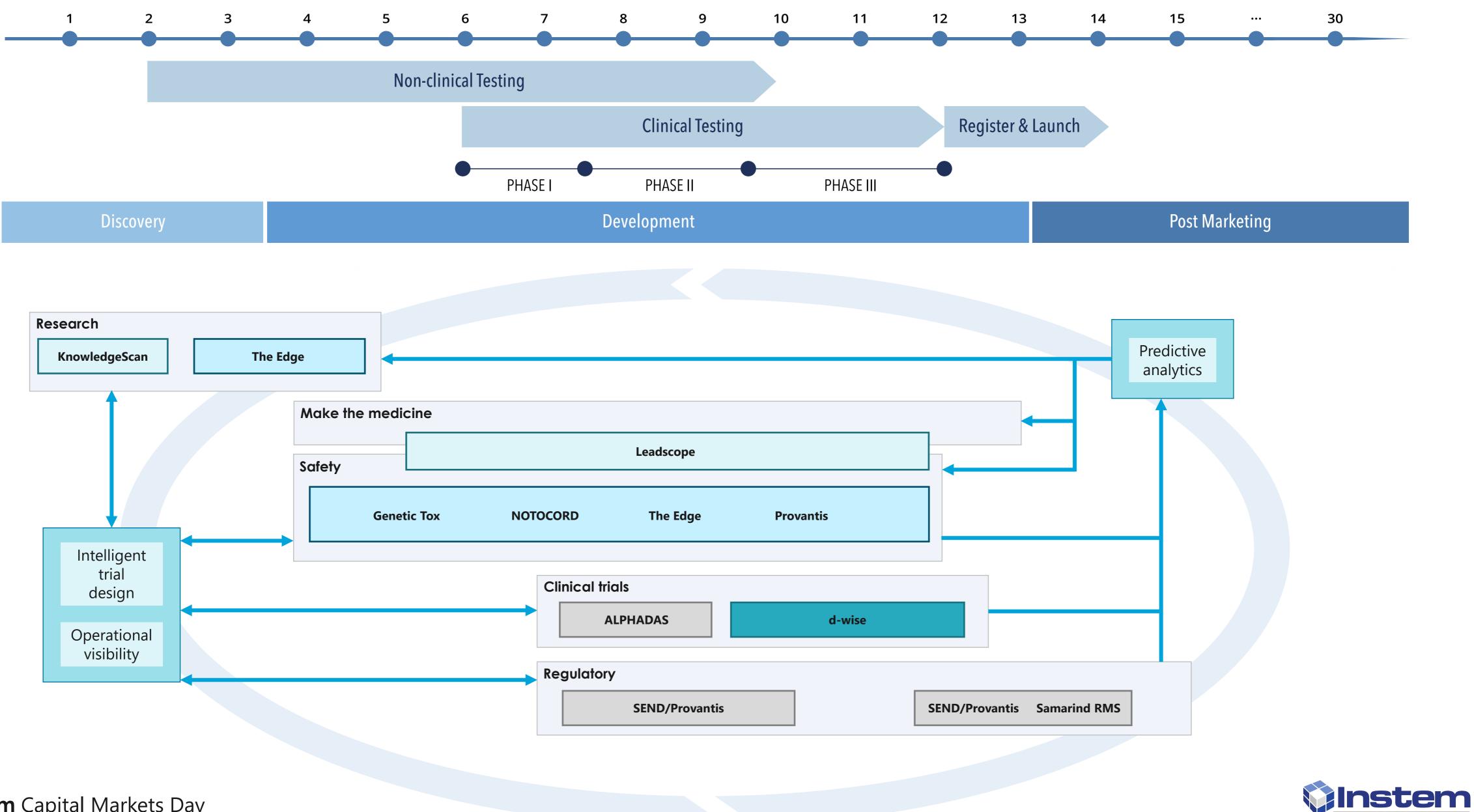


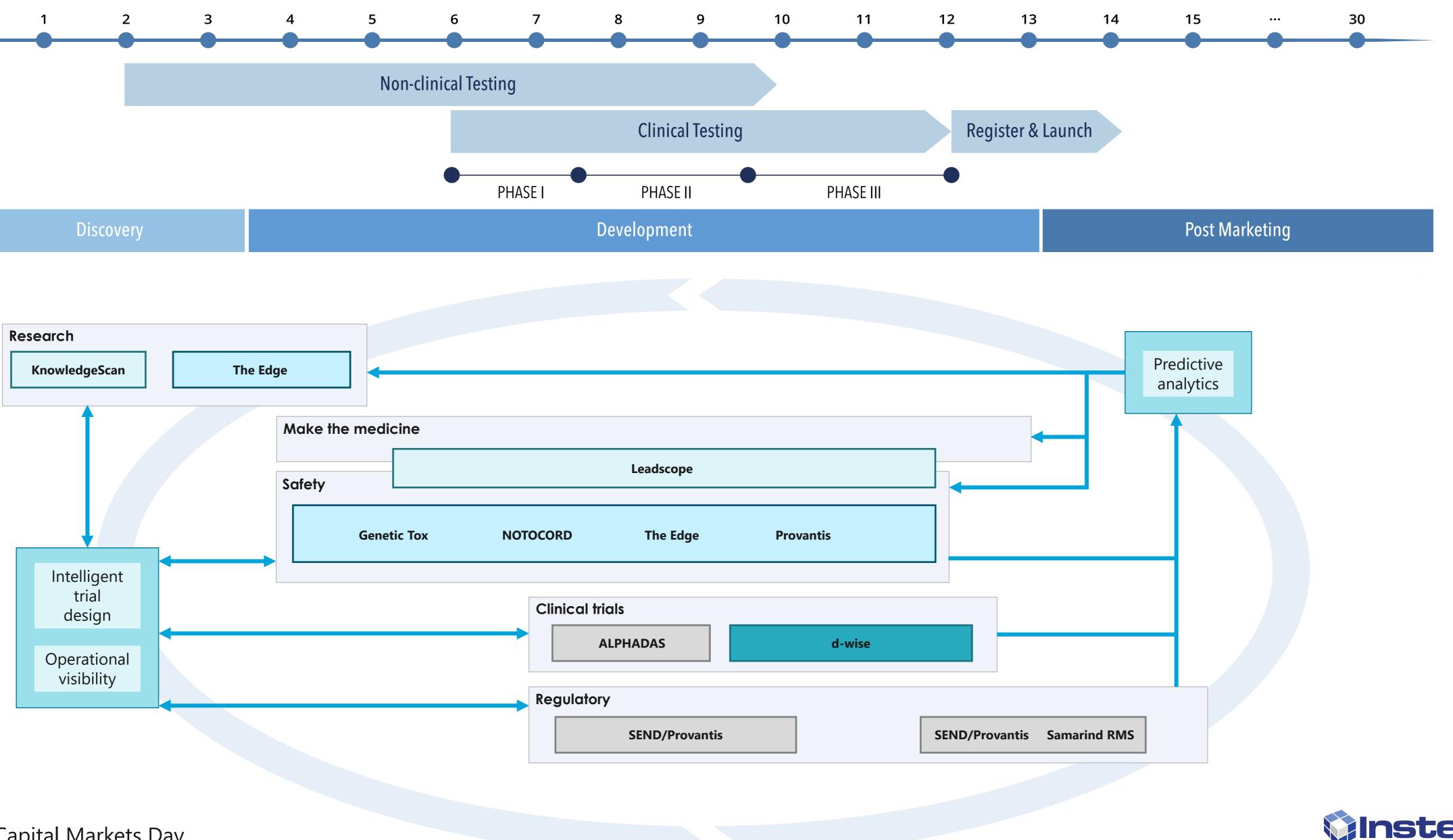












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Information Solutions For Life



BRINGING A NEW DRUG TO MARKET 13 years!

\$2.56bn!





Instem Information Solutions For Life

STUDY MANAGEMENT SOLUTIONS **OVERVIEW**



BioRails	e Morphit	ion BioHub
EProvantis Argrated preclinical software	Genetox Solutions	RECEIPTION OF THE SECOND SCIENCE Speeding up Research, Empowering Science
ALPHADAS ®		samarind
Leadscope®	KnowledgeScan™ Target Safety Assessment Service	Subbridget Sentence
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Notocord-hem[™] - The leading software platform for the acquisition, display and analysis of physiological signals

Genetox - Image analysis and data management solutions helping users better collect, manage, review and extract data while transitioning information into insight

ALPHADAS® - The leading eSource, Proactive EDC system for early phase clinical trials

Submit[™] - A suite of tools and outsourced services for the creation, management, visualization and pre-submission analysis of FDA SEND datasets

Samarind RMS[™] - A fully integrated software solution that has been purpose built to mirror the processes associated with acquiring and maintaining product licenses

KnowledgeScan[™] TSA - A technology enabled, informatics-based service to generate critical insights from immense and disparate scientific and medical 'big data'

Primary Solutions

Leadscope - In Silico Safety Assessment products & services to help researchers better predict potential safety outcomes

BioRails[®] - A comprehensive system for workflow-driven data management

Morphit[™] - Providing unique abilities for reading, managing and visualizing data from instruments and transforming raw data into validated results

BioHub[™] - A single centralized location for storage and seamless access to all corporate research data

Blur[™] - The leading software solution that automates anonymization of both documents and data through Natural Language Programming

Accel[™] - Cloud-based SCE with pre-loaded tools, applications & licenses for today's biometric team and CROS for sharing data, programs and analysis results

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Common Characteristic / Opportunities

- Scalable, Configurable Domain solutions
- Streamline the scientific process
- Aids decision making
- Many Common Customers
- Greater access to a broader range of • Data







Instem Information Solutions For Life

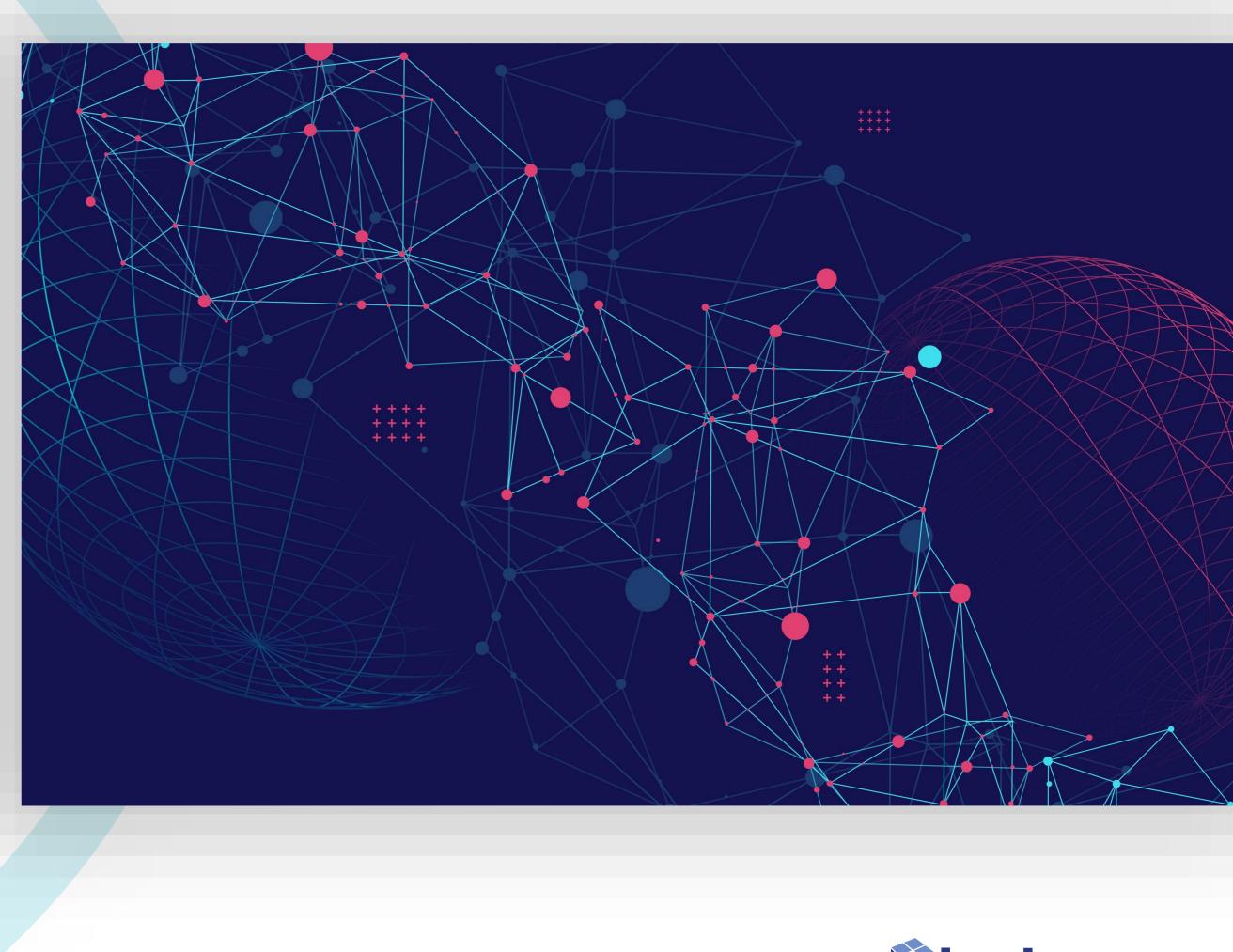
REGULATORY SOLUTIONS **OVERVIEW**



Introduction

- Instem a long history of delivering products to a heavily regulated industry
- Regulated industries bring opportunities:
 - Focus on quality •
 - Requirement for specialist knowledge
 - Steady flow of changes
- Section covers:
 - SEND
 - RIM (Regulatory Information Management)
 - Clinical Trial Transparency

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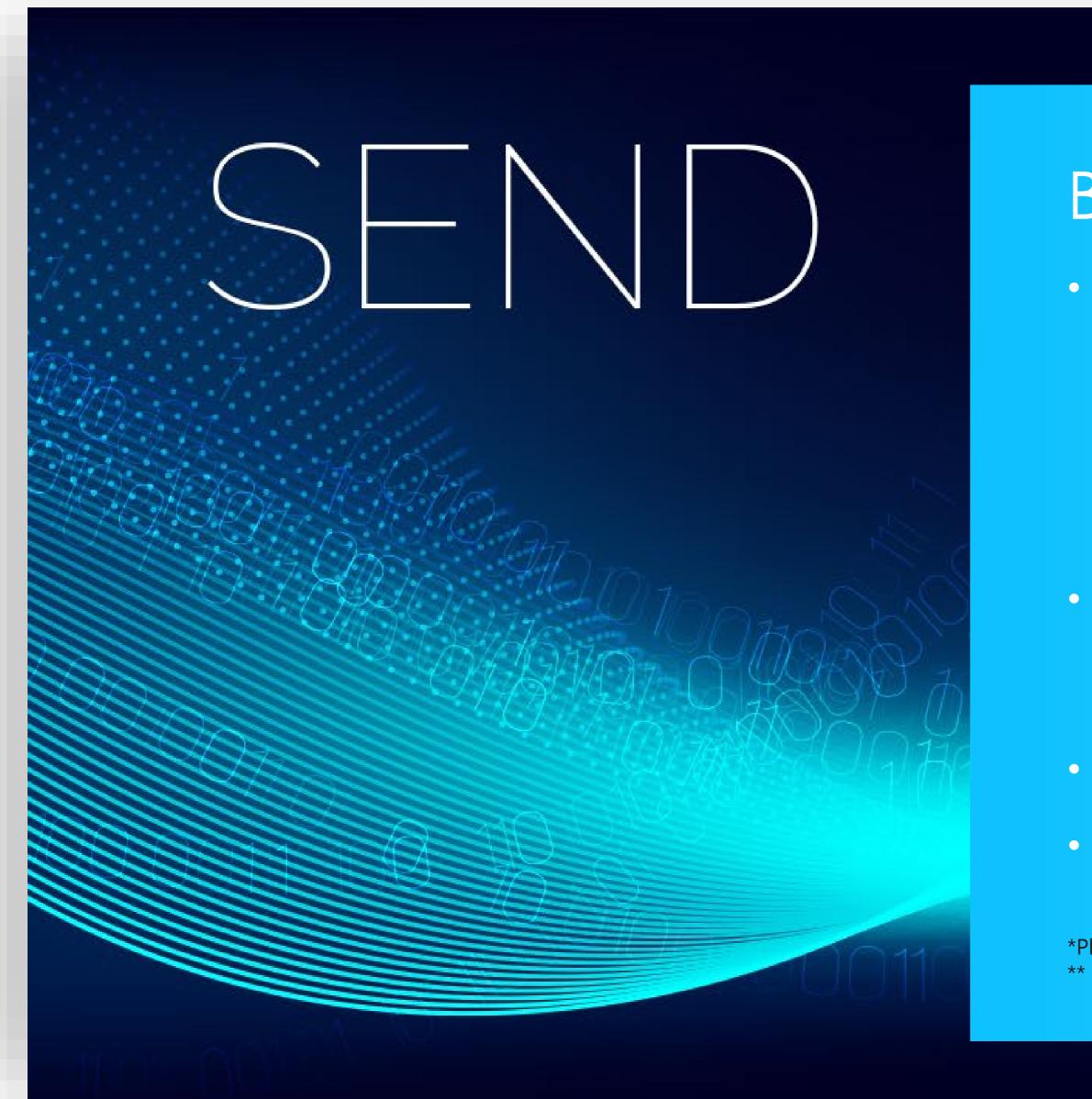






SEND





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BACKGROUND

• Every drug company has to submit data to FDA as part of the processes for testing and getting approval for a new drug.

- 17,737 candidate drugs in development*. Up by 9%.
- 8,000 nonclinical studies per year submitted to FDA**
- Prior to this, all of this data was submitted in PDFs and frequently re-typed for analysis by FDA reviewers.
- This data is submitted in a standard format called SEND.
 - The SEND standard was mandated in 2017
 - Standard is still extending to new study types

Market matured to point where exploitation is next step

"Instem is SEND" – the leaders

*Pharma R&D Annual Review 2020 ** Management estimate based on published FDA statistics







Instem & SEND

- We contribute to the creation and advancement of the standard
 - SEND is developed by CDISC
 - The standard continues to advance FDA just announced next extension
- We have the largest (and still growing) installed base of SEND creation software
- We have the largest independent outsourced SEND Services team
- We are expanding our products and services to exploit the existence of SEND • Growing demand for data science approach to nonclinical data • To spot safety issues early, shape development programmes, accelerate product
 - - launches
- Appetite for conversion of historical studies to populate data warehouses

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SEND & SDTM

- SEND standard is "built on" SDTM
- SDTM is the clinical equivalent to SEND
 - i.e. SDTM standard required by FDA for clinical data submissions
- Significant interest in translational potential combining nonclinical & clinical data
 - eTranSAFE, Biocelerate
- Instem & d-wise uniquely placed to exploit











R

Regulatory Information Management



RIM

Background

- Drugs, medical devices, veterinary products licensed to be sold in each jurisdiction
- Licences contain a lot of detail: •
 - Product, manufacturers, ingredients, components, labelling,...
 - Frequent changes, multiple licences & documents
- High levels of regulatory changes
 - Pharmaceuticals: IDMP, E2BR3, eCTD,....
 - Medical Devices: MDR, IVDR
 - Veterinary products: NVR









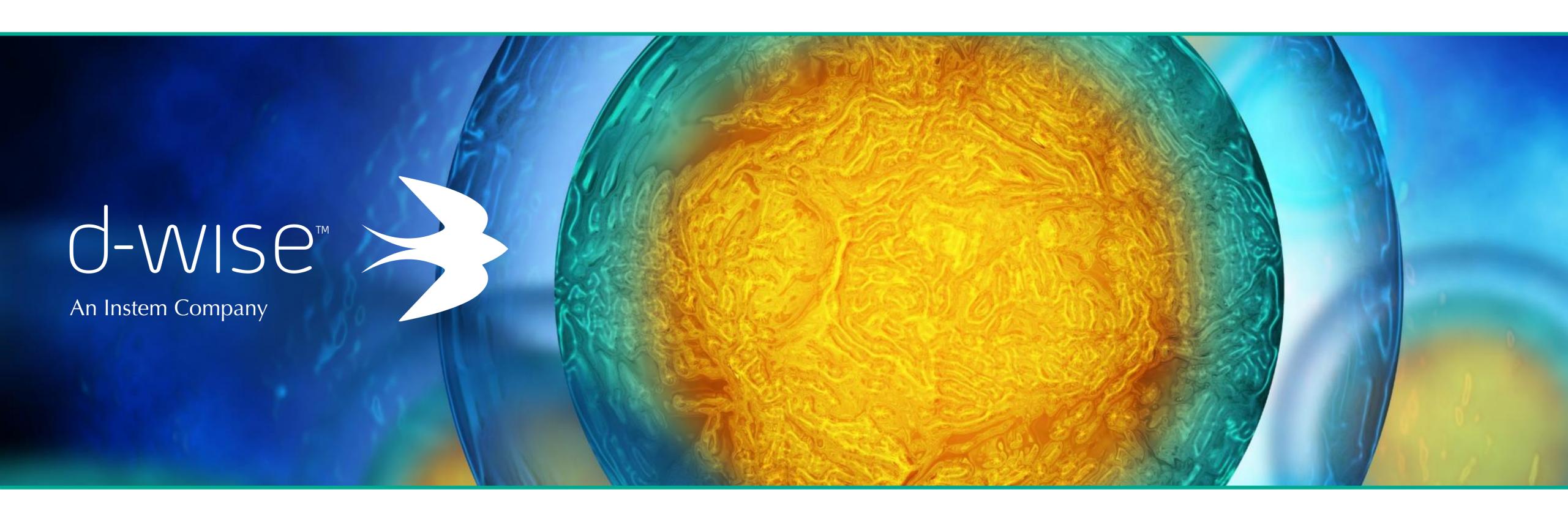
RIM Solutions

- Historically document-based solutions
- Pharmaceutical market highly competitive
- Medical devices market under-served
 - Slower to introduce standards
 - Greater COVID impact
 - Few vendors

samaring RMS

- Pioneering data-based solution, xEVMPD
- Handles Medical Devices, Pharmaceuticals and Veterinary products
- Broad functional coverage
 - Registrations, Document management, eCTD, Drug Safety
- Strong recurring revenues





Clinical Trial Transparency The people you trust. The software you need.

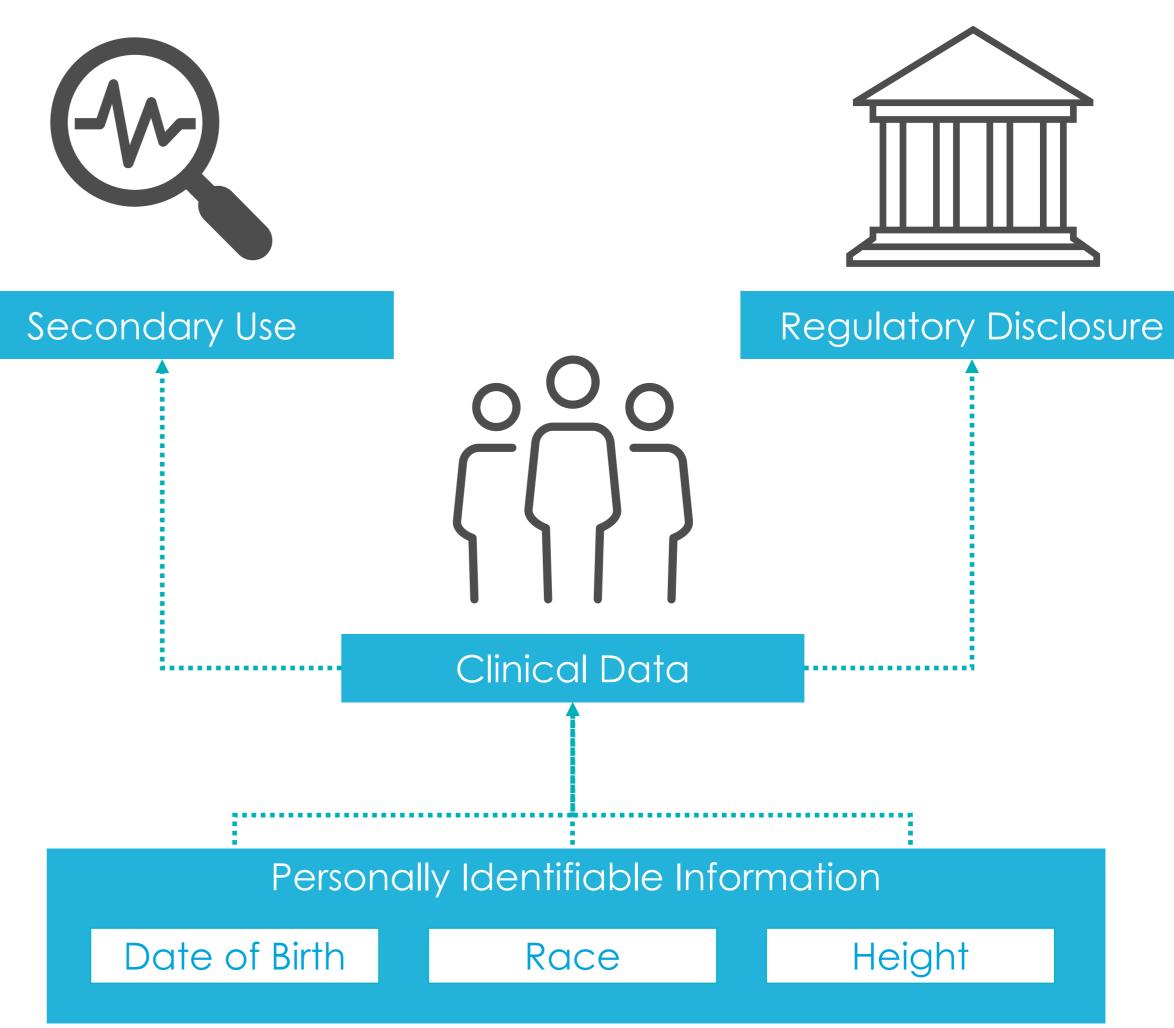
Transparency Primer

Clinical data and documents contain personally identifiable information which is protected under privacy laws and is collected for an intended use.

- **Regulatory Sharing** Health Authorities require Ο Sponsors to publish de-identified clinical documents to comply with regulations
- **Secondary Use** re-using de-identified clinical Ο data enables clinical innovation and research initiatives
- **Privacy Regulations** require shared data to be Ο dissociated from the patient so the patient is no longer identifiable



How can sponsors enable regulatory sharing and secondary use in a manner consistent with protecting patient privacy and intended use?









Value to Sponsors Remove barriers to clinical data sharing and transparency and respect and honor the contributions of clinical research participants.

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What We Support

Canada

 Health Canada Public Release of Clinical Information

European Union

- EMA Policy 0070
- ✓ EMA Policy 0043

Corporate Transparency Policies

- Secondary Research Requests
- ✓ Internal Re-use of Data
- Public Commitments



Redaction and Anonymization of Documents and Data across regions and regulations

Industry Challenges





COMPLIANCE

- Conflicting regulatory guidelines
- Evolving standards
- Regulations increasing and penalties for noncompliance

RESOURCES

- Few dedicated people
- Inconsistent demand with inability to scale quickly
- Specialized skill set





TIMELINES

- cycles are event driven and hard to anticipate
- regulatory timelines stress limited resources

TOOLS & SOFTWARE

- Scripting tools are manual, time consuming, labor intensive
- Legacy data and documents not created with public disclosure in mind
- Lifecycle management process complex





How We Support Clients

People

 clients can fully outsource their transparency needs to the d-wise clinical trial transparency team

Process

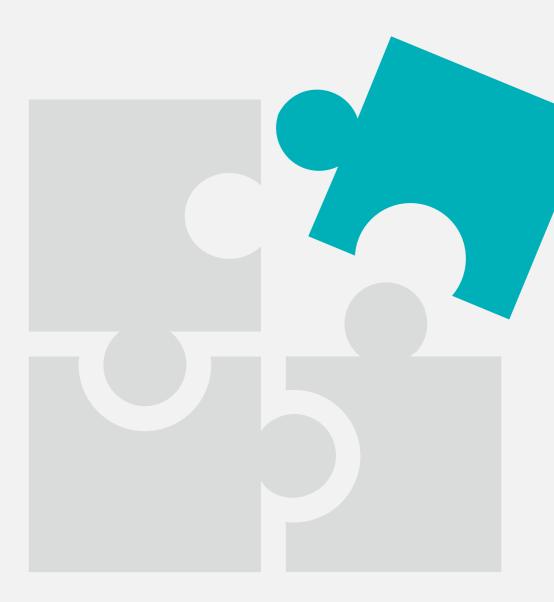
- clients can use our processes to deliver deidentified documents based on quantitative risk assessments
- clients can engage our team's expertise to develop their internal strategies, policies, and processes

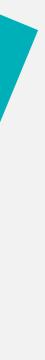
Technology

- clients can depend on our tech-enabled outsourced services, or
- can adopt our technology to provide their business with enterprise-class capabilities for deidentification and risk measurement

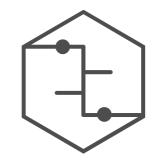
How can sponsors enable regulatory sharing and secondary use in a manner consistent with protecting patient privacy and intended use?

Sponsors trust d-wise Clinical Trial Transparency team to provide the people, process, and technology to enable clinical trial transparency.





Clinical Trial Transparency Offerings Portfolio



SOFTWARE

- License
- NLP Training
- User Training

- Data, Documents, and Risk Partnership
- An integrated solution for • Anonymization Report • Single Submission or





SERVICES

STRATEGY

- Regulatory Consulting
- Quantified Risk Consulting
- Submission Strategy





d-wise Differentiators



Experts in EMA Policy 0070, Health Canada's Public Release of Clinical Information, internal sharing and building transparency strategy

Members of the PHUSE Data Transparency Working Group, the EMA Technical Anonymization Group and the DIA Transparency Group

Top 10 pharma companies)

data, documents, and risk

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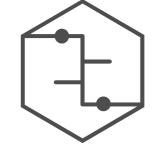




Proof of Success (Validated by multiple



An integrated end-to-end solution for



Flexible Options to meet clients where they are:

- ✓ Software (Blur) Saas
- ✓ Outsourced Services
- ✓ Transparency Strategy







Clinical Trial Transparency By the Numbers



SUBMISSIONS

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SUBMISSIONS



HAPPY CUSTOMERS

DATASETS **DE-IDENTIFIED**

DOCUMENTS ANONYMIZED

PROCESSED



Select Clients









REGENERON



moderna











People You Trust. Software You Need.

Canada

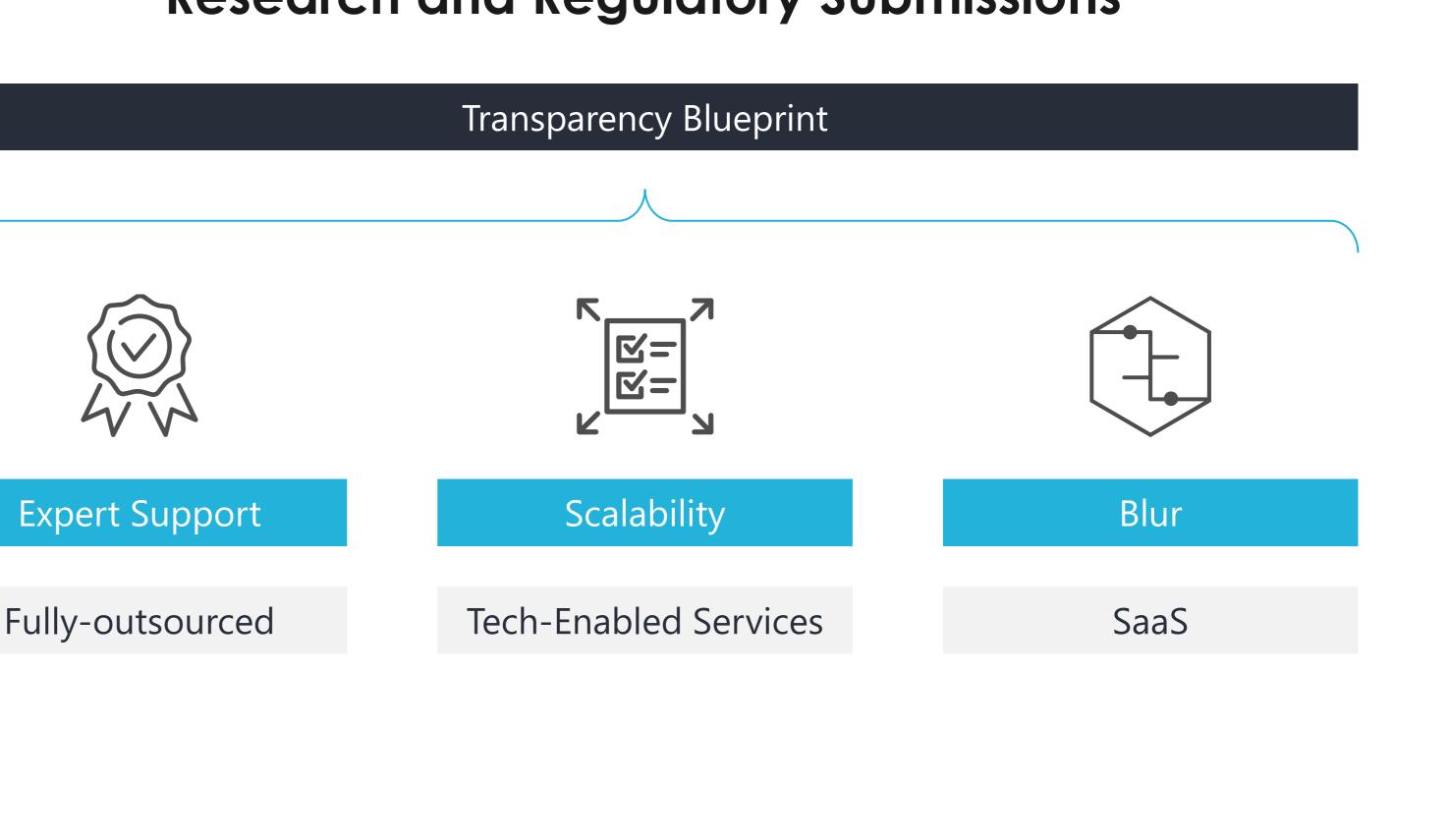
 Health Canada Public Release of **Clinical Information**

European Union

- EMA Policy 0070
- ✓ EMA Policy 0043

Corporate Transparency Policies

- Secondary Research Requests
- ✓ Internal Re-use of Data
- Public Commitments





Research and Regulatory Submissions









- Founded in 1997, acquired by Instem in 2019
- Scientific leaders in computational toxicology
 - High quality scientific engagement
- **Research Collaboration** Agreement with the US Food and Drug Administration with multiple centers
- Solutions are extensively used • across multiple industries



What do Leadscope do?

- - decisions
 - areas
- impurities, ...)
- Supports industry priorities
 - •
 - Avoiding late-stage failures
 - Improving productivity

Develops toxicity tests to either replace or supplement a traditional toxicity experiment Predicts the safety of chemicals on the computer Uses historical data to make more informed

Accepted by regulatory authorities in certain

Focus on chemicals (New Chemicals Entities,

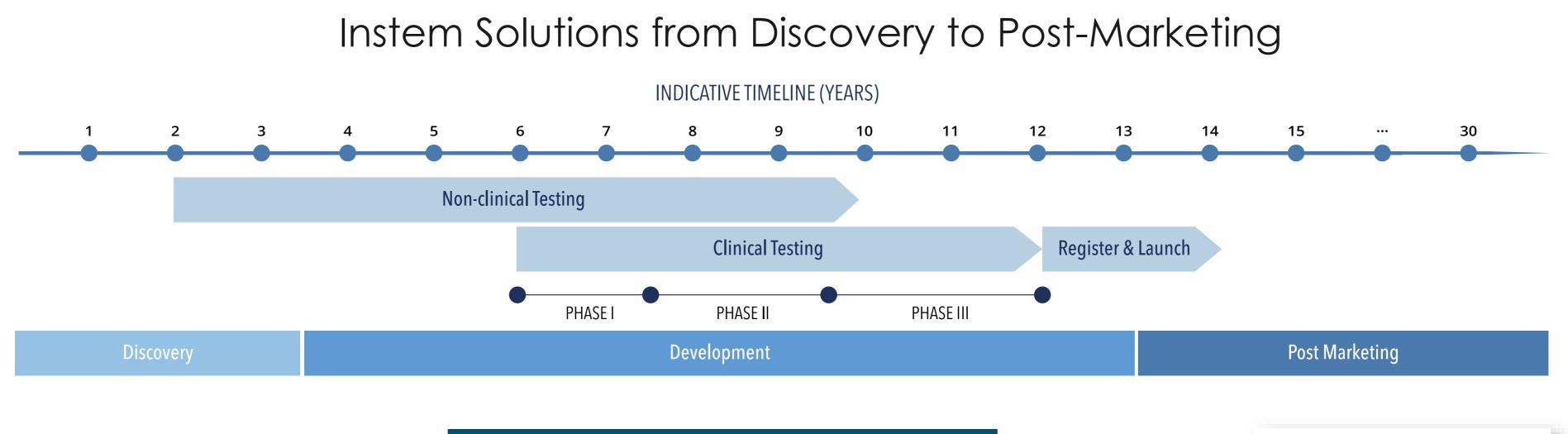
3Rs – reduce, refine, replace animal experiments





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Where is Leadscope primarily used?



Pharmaceutical impurities

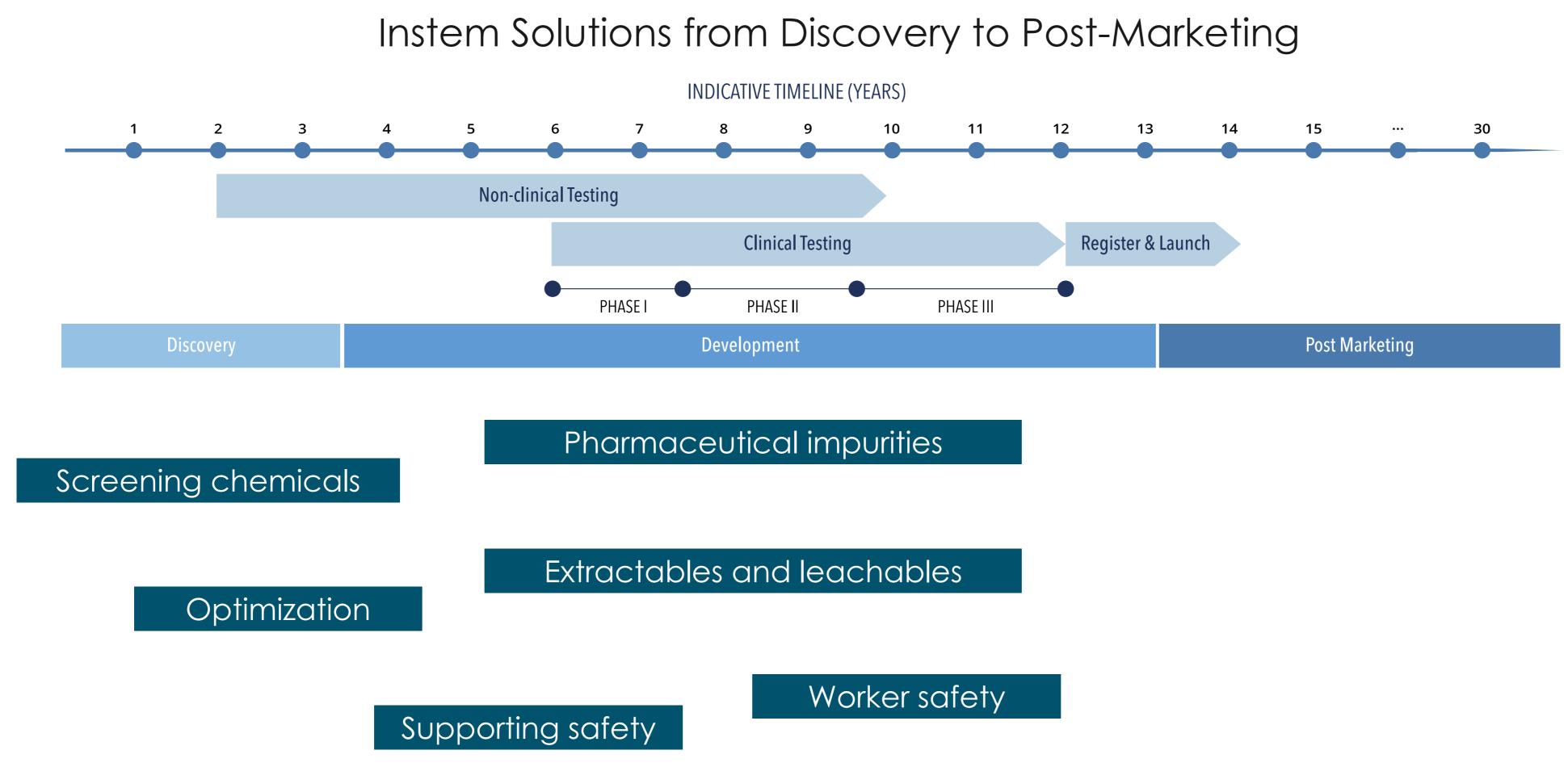
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M7 Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk

Guidance for Industry

J.S. Department of Health and Humar Food and Drug Administration Center for Drug Evaluation and Research (CDER) Center for Biologics Evaluation and Research (CBER) May 2015 ICH





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Where else is Leadscope used?

Transportation



How is Leadscope licensed?

Recurring annual licensing

- Software: Desktop, Client-Server, Cloud-based, Webbased
- Databases: Over 200,000 chemicals and 500,000 toxicity studies
- Computational models: Individually license computational models
 - Genetic toxicity, Acute toxicity, Skin sensitization, Irritation/corrosion, Carcinogenicity, Reproductive and developmental toxicity, Endocrine activity models, Organ toxicity (liver, kidney, cardiac), Neurotoxicity, Bioactivation, Abuse liability, Environmental toxicity

Consulting programme

Royalty payments when Instem's computational toxicology technology used within consulting engagement





INSTEM TECHNOLOGY-ENABLED SERVICES



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KnowledgeScan[™] Target Safety Assessment Service



KnowledgeScan[™] Target Safety Assessment Service



- A platform encompassing, bigdata workflows, advanced dataanalytics, AI and scientific expertise
- The basis of a technology-enabled service focused on Target Safety Assessment (TSA) launched in 2017
- Exceeded intial growth expectations
- Innovations in drug development driving adoption (e.g. gene editing)



What does a KnowledgeScan TSA do?

- - drug safety
 - Uses historical data to provide medical insight and enable more fully informed decisions
 - In silico, AI technology enabled service signaling pathways)
- Focused on biology (genes, mRNA, proteins,
- Supports industry priorities
 - Improving productivity
 - Avoiding late-stage failures
 - 3Rs reduce, refine, replace animal experiments

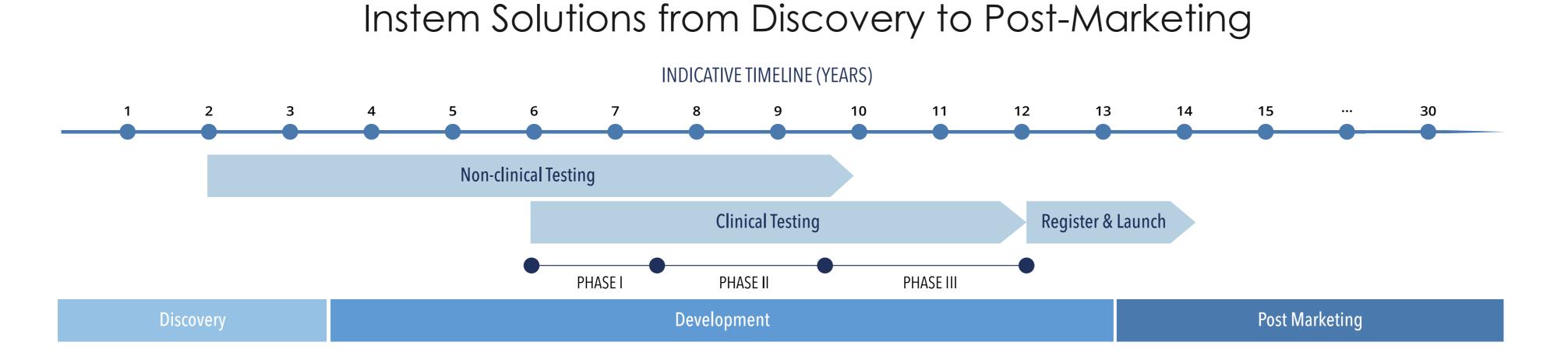
Provides an assessment of the potential hazards associated with modifying the function of proteins Increasingly the earliest formal assessment of





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Where is KnowledgeScan primarily used?

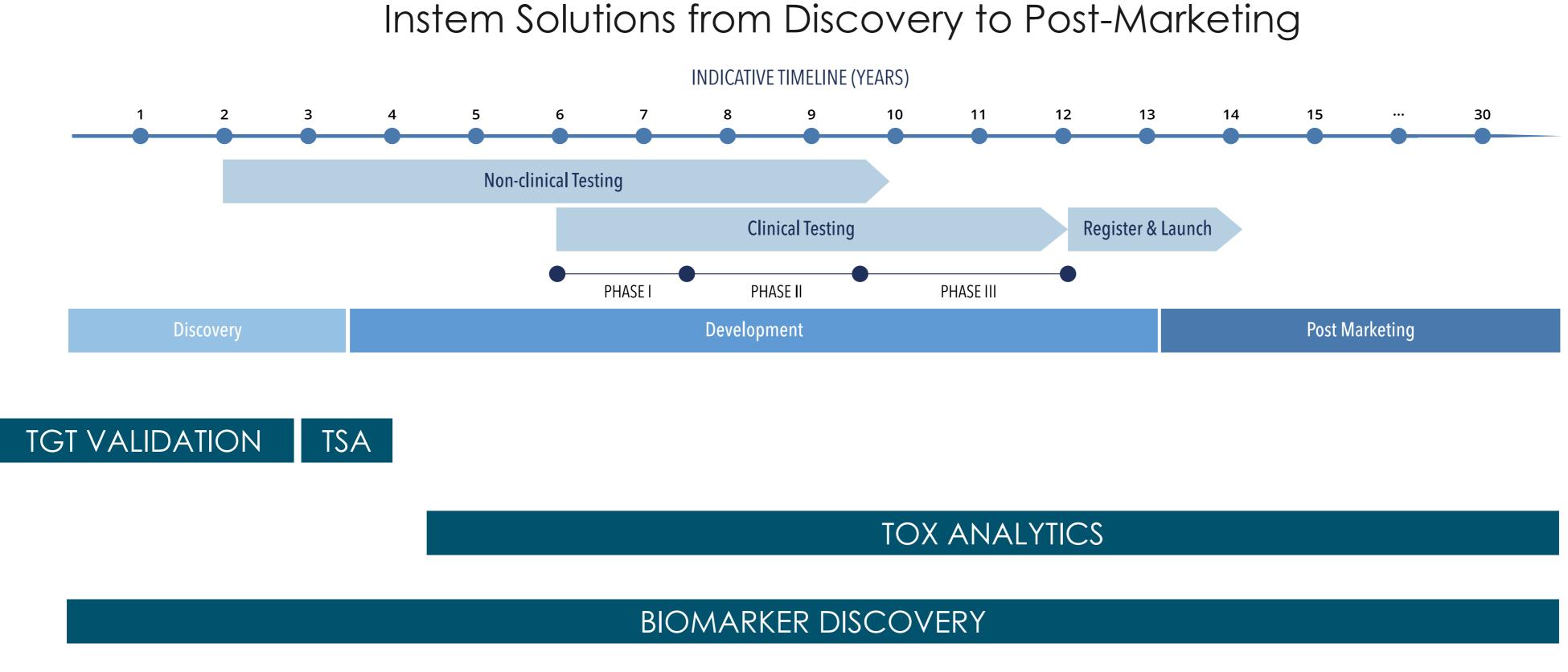




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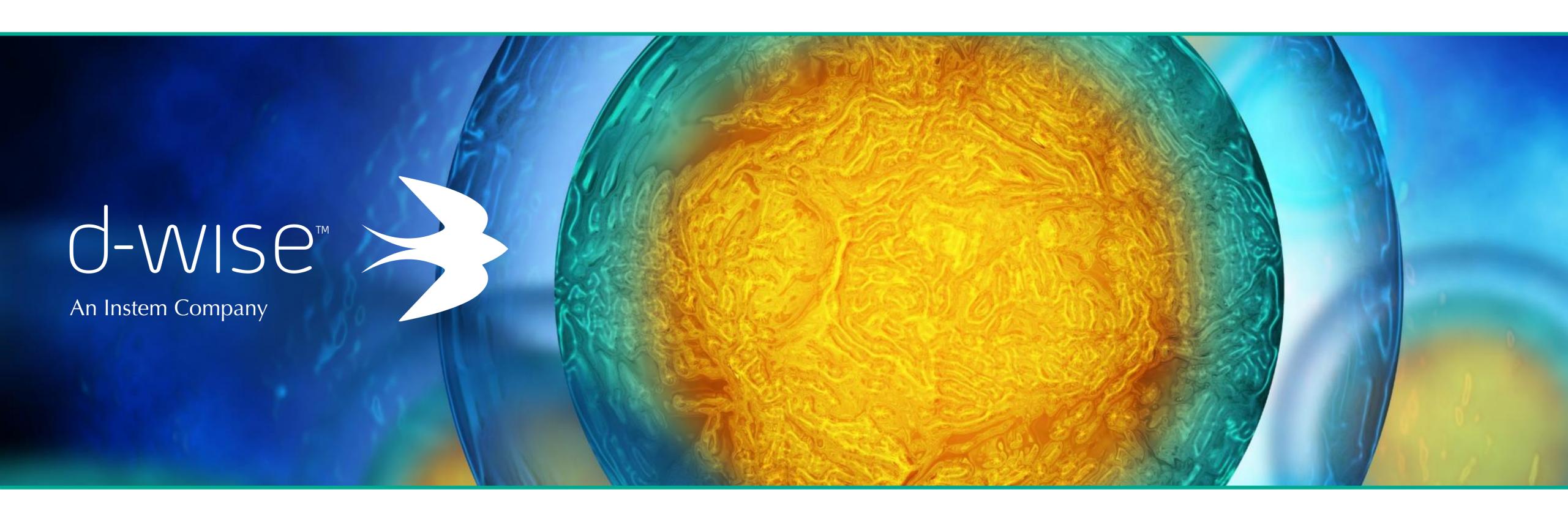
Where else can KnowledgeScan used?



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TECHNICAL DUE DILIGENCE





Clinical Trial Acceleration

Value to Life Sciences

Open, flexible and validated solutions that enable scientific focus and increased speed-to-market and transparency

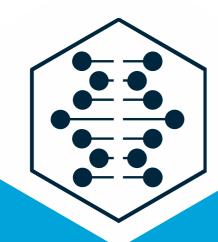
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Domain Expertise



CLINICAL TRIAL ACCELERATION

Biometric & Data Science Solutions



STRATEGY



SERVICES



Clinical Systems Modernization

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CLINICAL TRIAL TRANSPARENCY

Disclosure & Transformation Solutions



STRATEGY



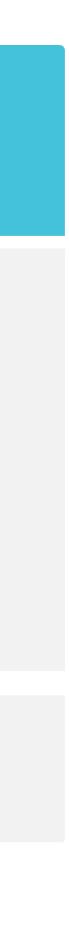
SERVICES



PRODUCT

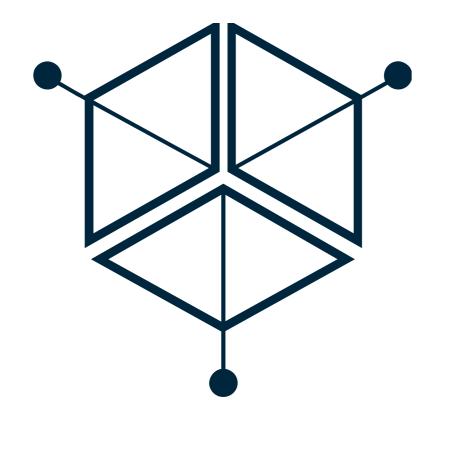
Anonymization & Risk Measurement

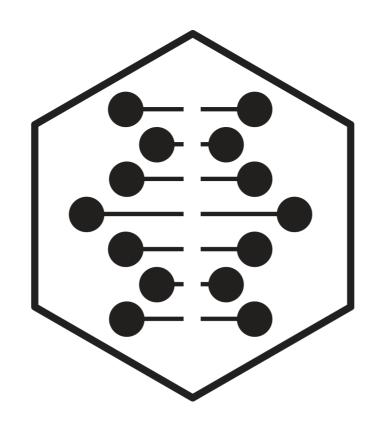






Market Segmentation



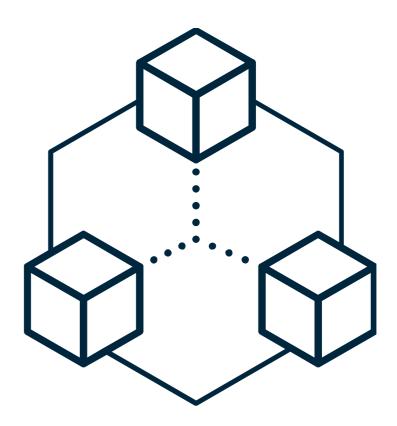


Accel

Acceleration Services

Mid-Market

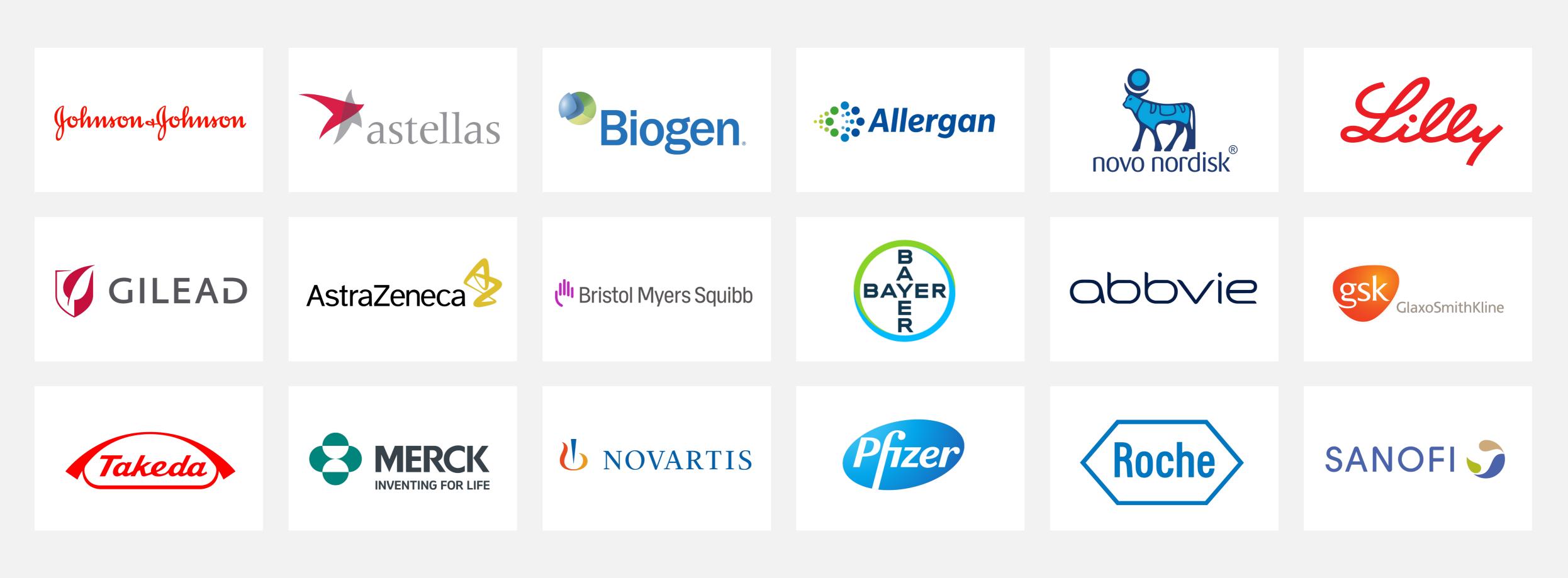
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Aspire

Enterprise







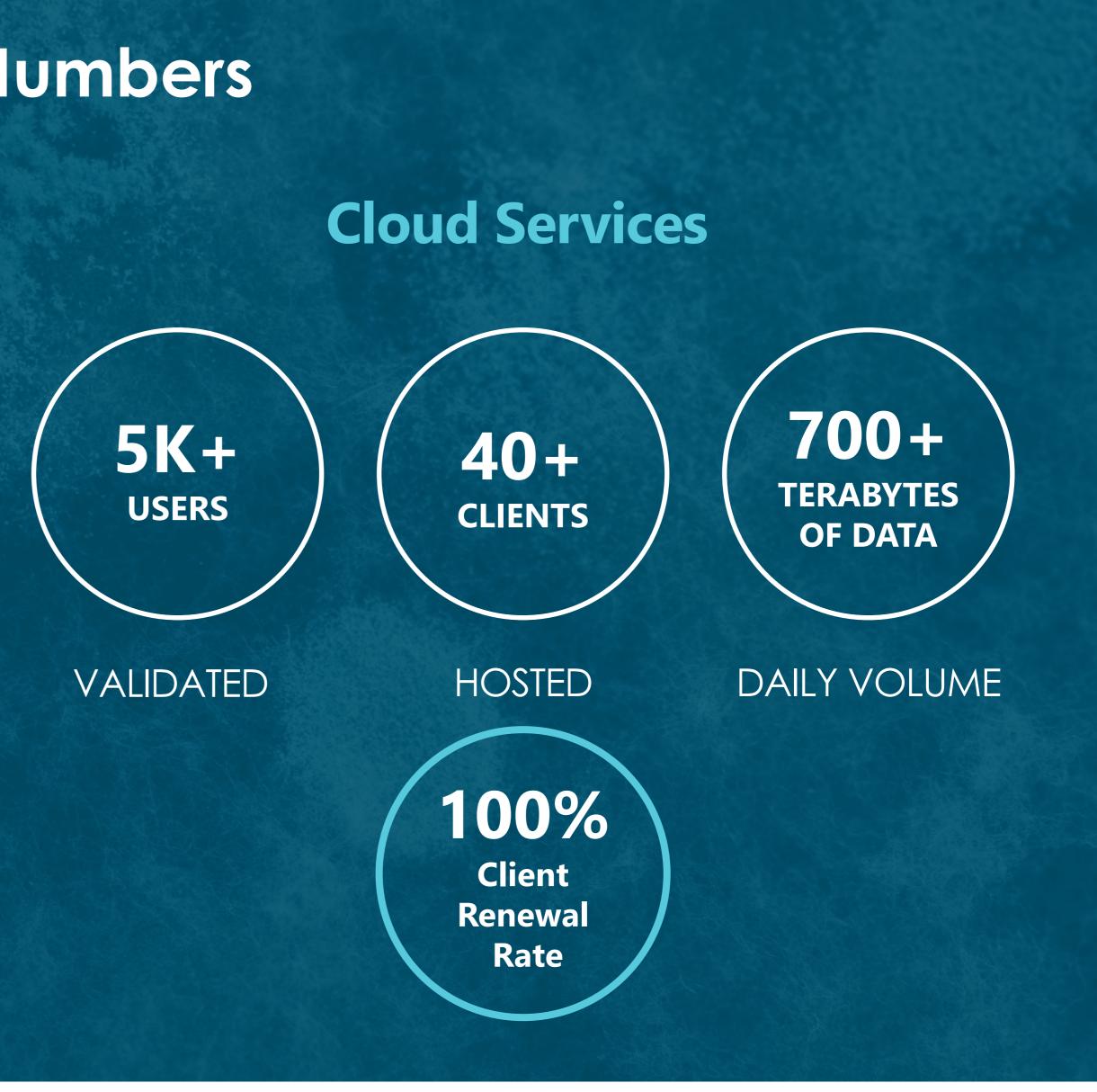


Clinical Trial Acceleration By The Numbers

Thought Leadership



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The Accel Solution



The Accel Platform

- Compliance. Reliability. Performance. \checkmark
- Validated SAS Environment \checkmark
- Designed and Managed by SAS Experts \checkmark
- ✓ Aligned to Best Practices
- Fully-Managed Infrastructure
- Application Support

* Configurable & extendable to include other tools: EAST, nQuery, WinNonLin, StatXact, Spotfire, JReview, etc.

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Key System Capabilities



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Data Ingestion & Exchange

Solution supports:

- Integration with Clients' Network Storage Solutions
- Data Exchange with CRO's and vendors

Data Storage

Solution Supports:

- Clinical Data Repositories
- Configurable security model





Data Analysis

System provides:

- SAS, R & Python
- Supporting productivity tools
- Version control

System Operations

System provides:

- Role-based permissions
- 24x7x365 Managed Support





Managed Services

Delivery Model

- Global team (US, UK, EU, India)
- Online ticketing portal
- Priority-based service
- SLA covering response time

Services

- System administration
- Data administration
- Validation management
- End-user support
- Monitoring / troubleshooting / performance tuning
- Adoption support (on-boarding, end-user training)
- Disaster recovery



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CTA Services



CTA Services

Discovery and Blueprint

- Current State Assessment
- Technology Roadmap
- Future State Blueprint

Planning and Design

- Process Optimization & User Experience
- Program Governance
- Solution Architecture

Build and Integration

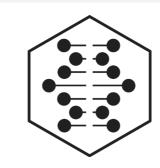
- Agile Build and Deployment
- Integration Map
- Migration Plan and Execution

Validation, Training, and Adoption

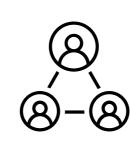
- Plan/Execute GXP Validation
- Create/Manage Change Management Plan
- User Workflow Focused Training

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ACCELERATION SERVICES



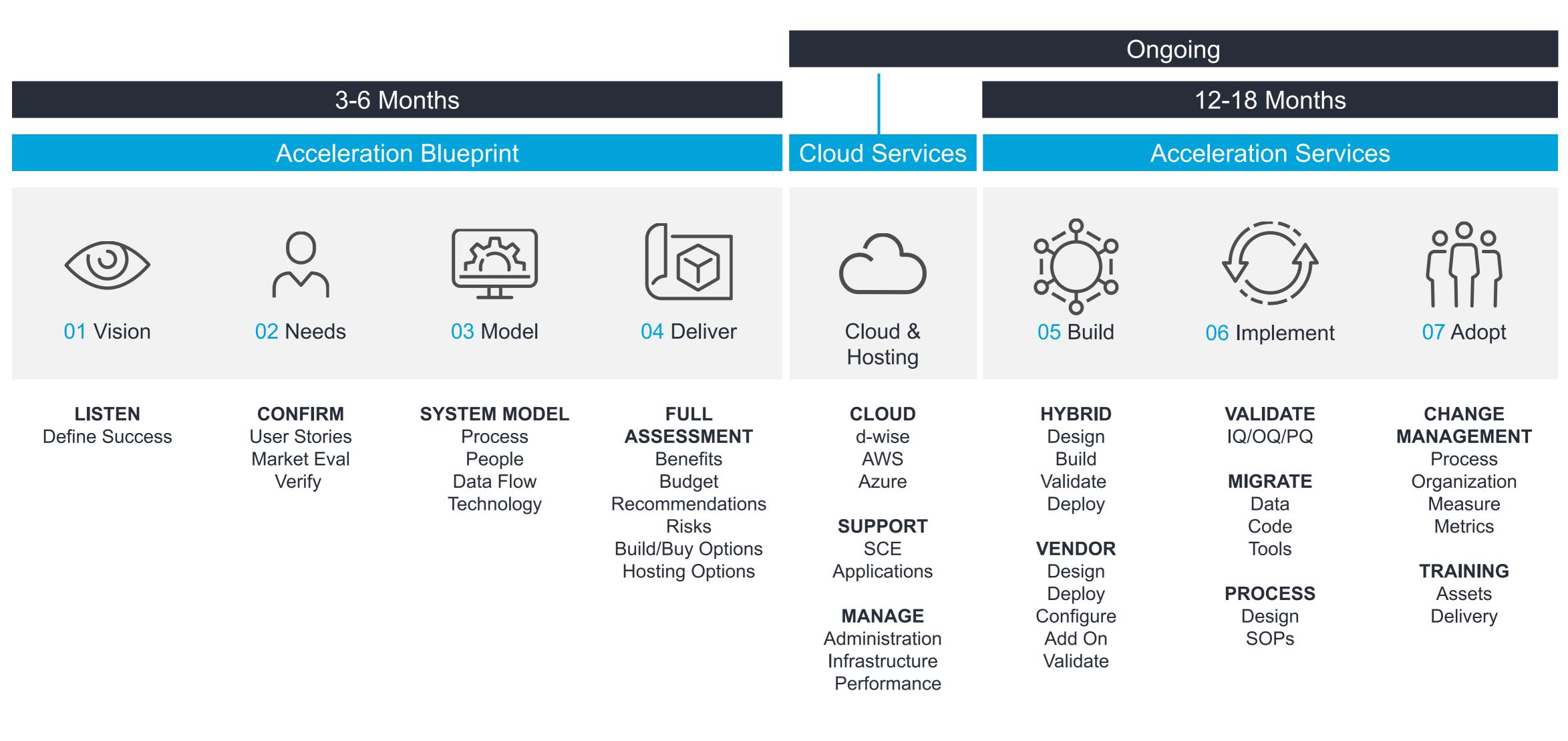
ACCELERATION ADOPTION







Thought Leader and Trusted Partner to Top Pharma









Aspire



Trends Summary

d-wise market research findings

 \checkmark SCE >80% of Top 20 Sponsors chose a custom SCE over a COTS solution

Trending Up

Fit for purpose solution built for client



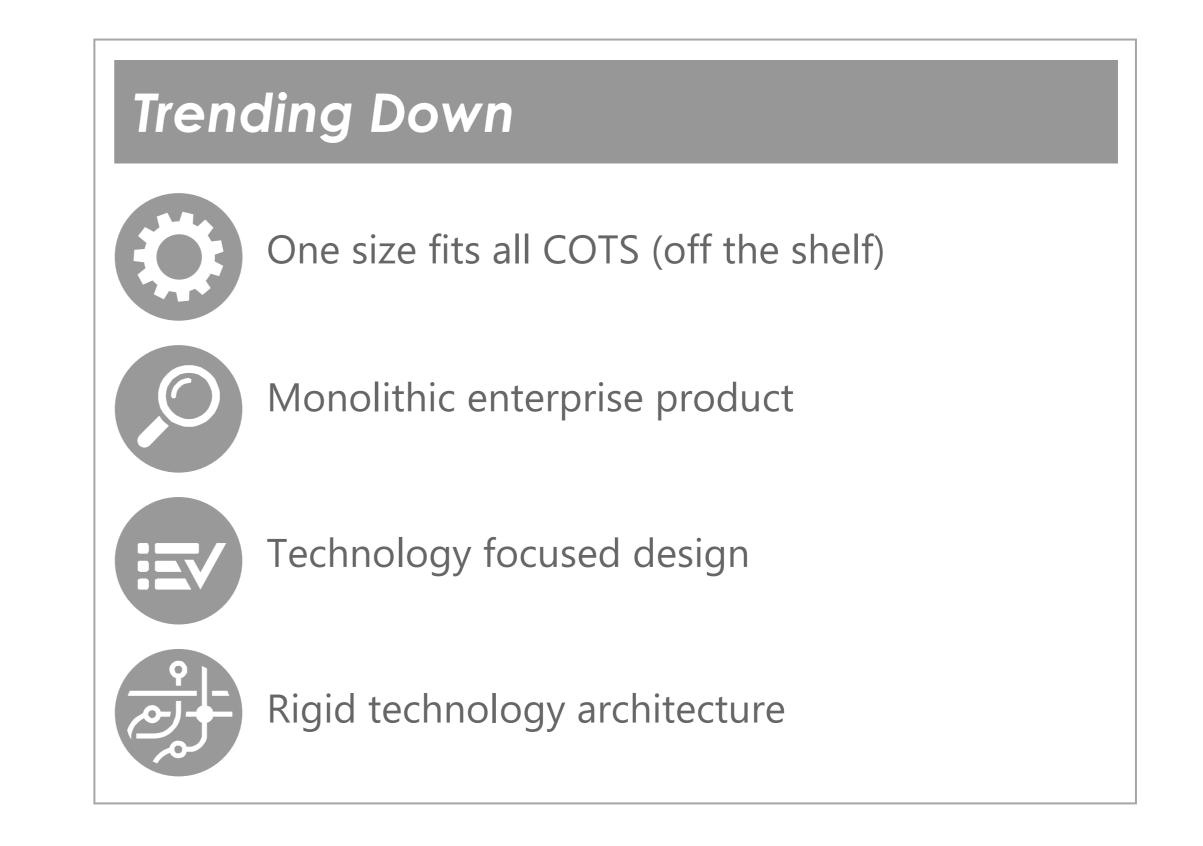
Flexible and Scalable cloud-enabled architecture

Human-centered design



Technology agnostic - modular architecture

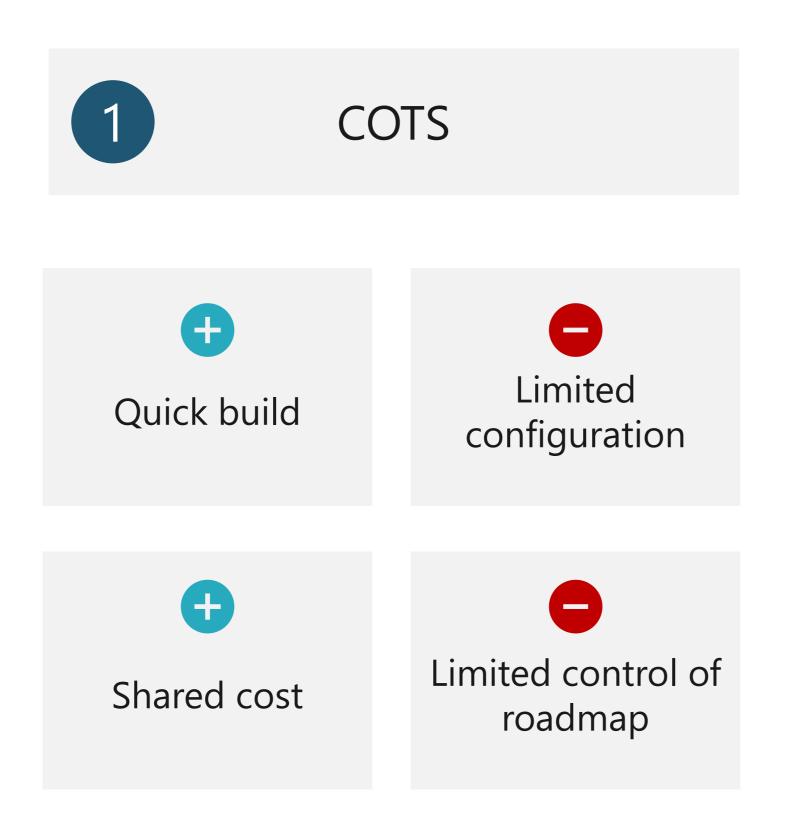
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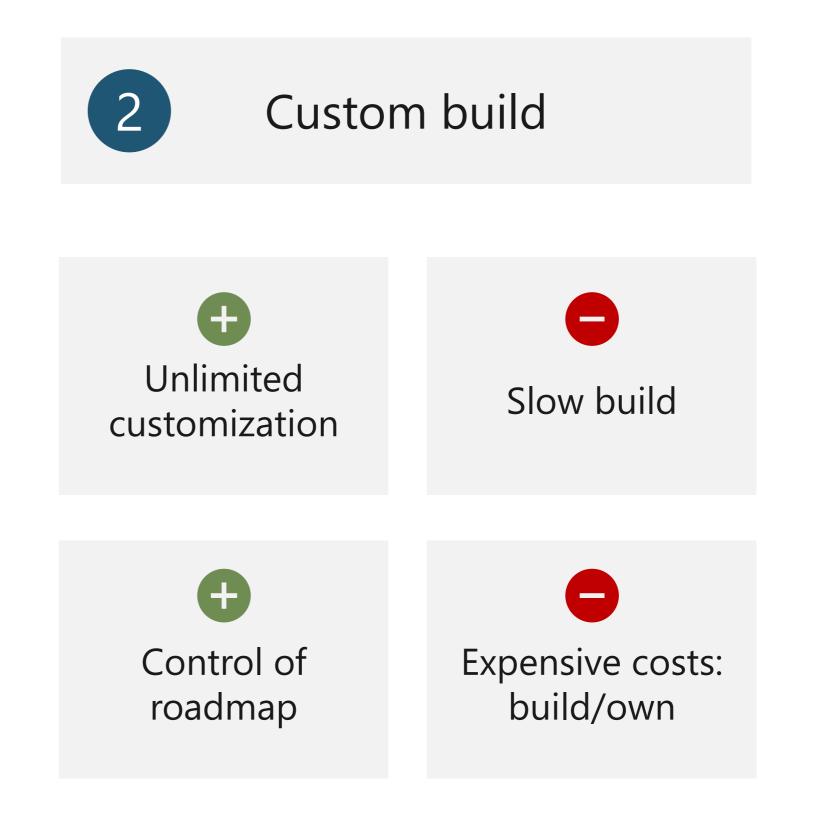


CURRENT PARADIGM: BUY vs BUILD



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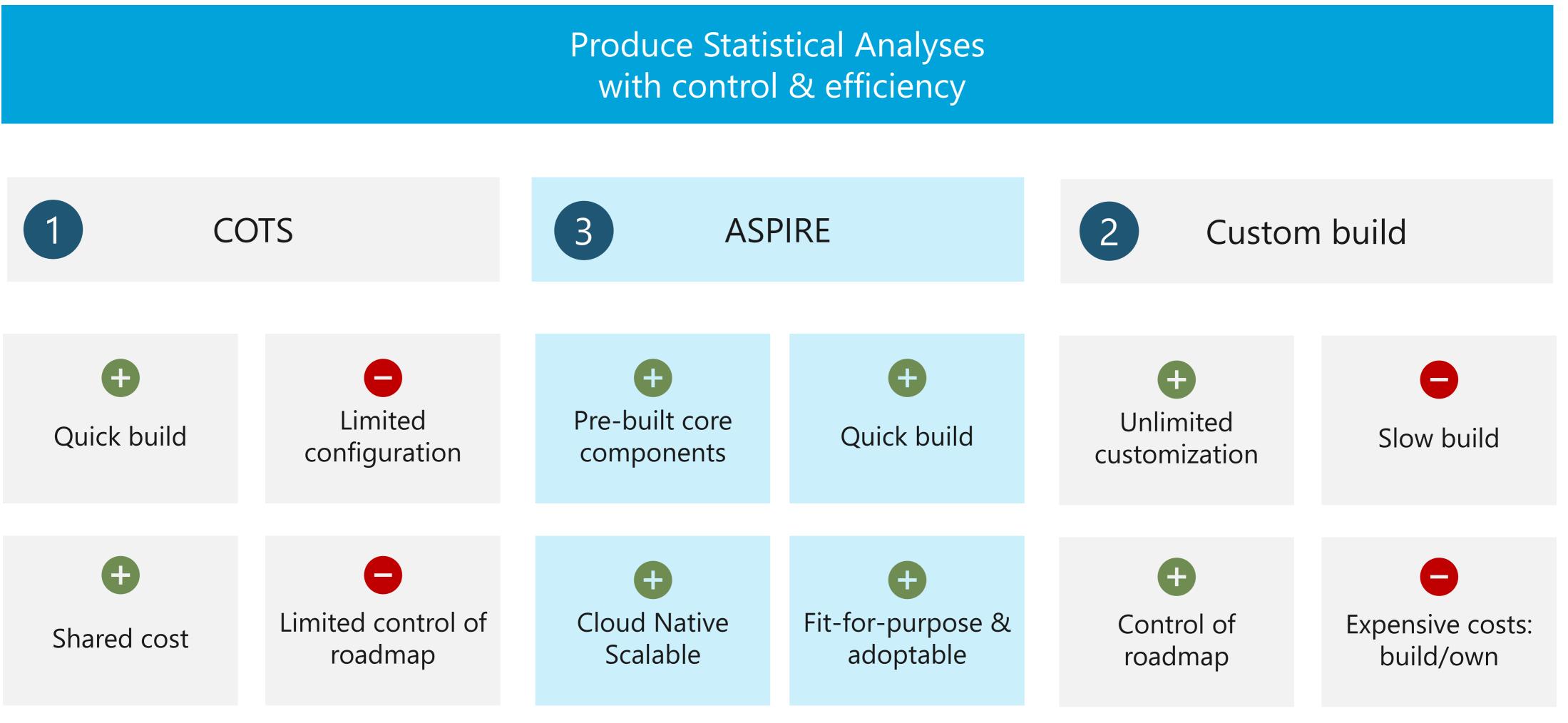
Produce Statistical Analyses with control & efficiency







ASPIRE: THERE IS ANOTHER OPTION

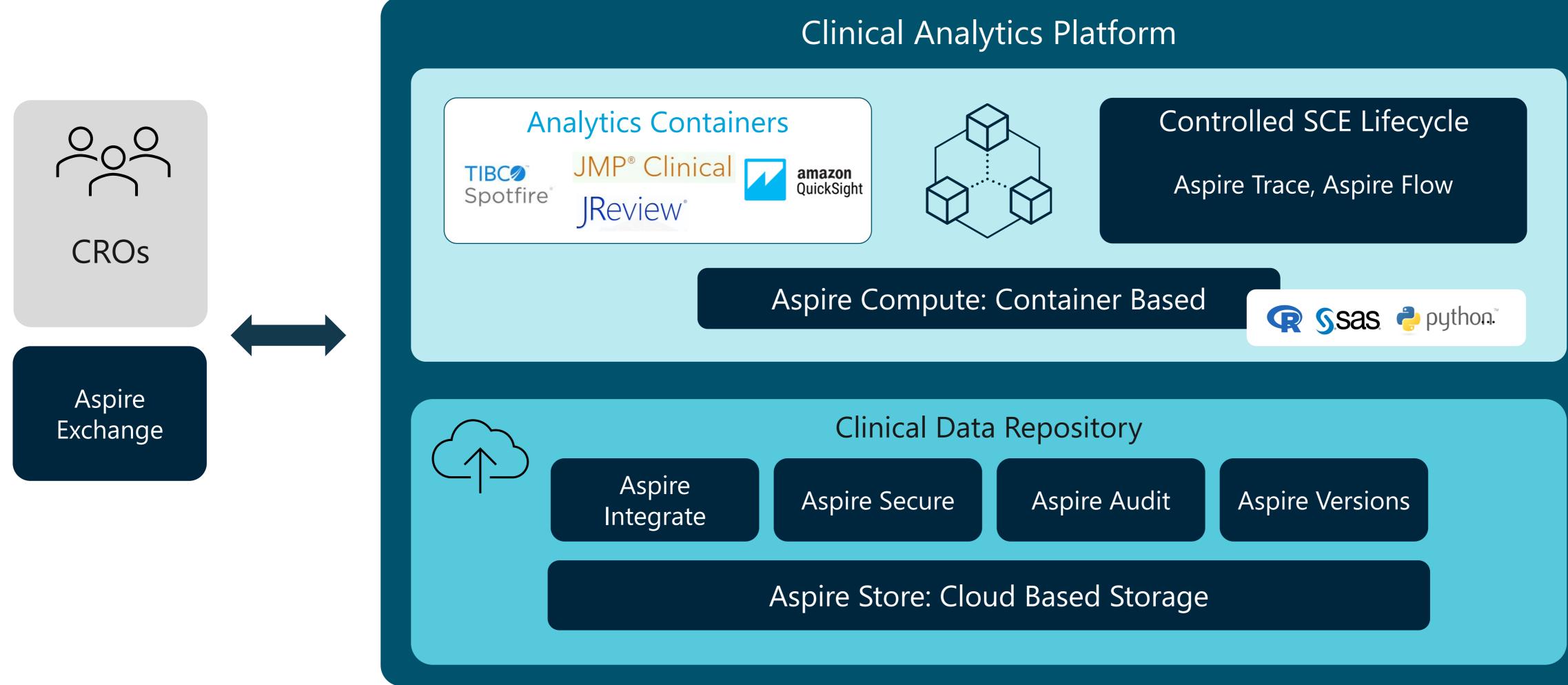


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Aspire – A Clinical Analytics Platform



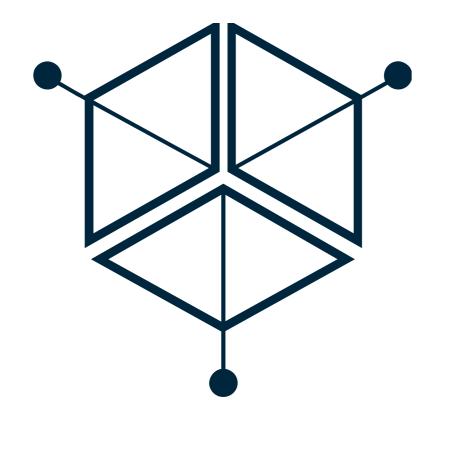
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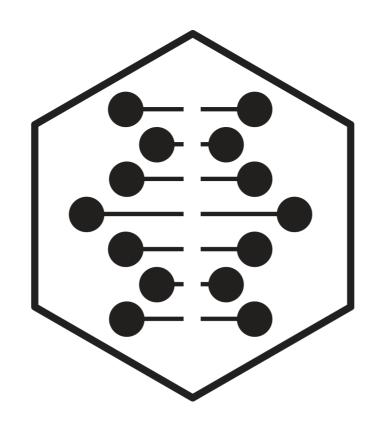






Market Segmentation



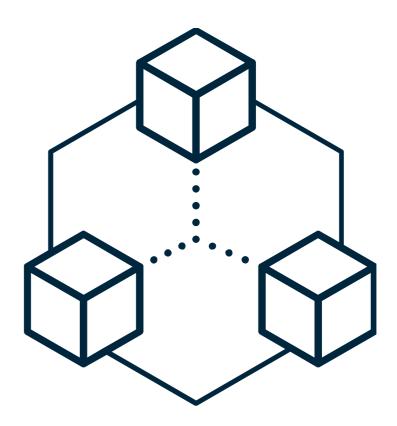


Accel

Acceleration Services

Mid-Market

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Aspire

Enterprise



Why d-wise?

The experts at d-wise understand the importance of change management in user technology adoption. Our teams are focused on delivering use-specific, integrated clinical analysis solutions in the cloud, delivering functionality today with a design for the future.

Two decades of clinical analytics solution implementation

Representative leaders in leading industry organization

Solutions every phase from data collection, submission to sharing

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Deep expertise in SAS, clinical development, data science & technology

Trusted by hundreds of companies to lead clinical system modernization











Steve Mason

Co-Chief Operating Officer Altasciences

Instem and Altasciences

- Evolution of early-phase drug development research in past two decades
- Instem is a leader in supporting CROs and Biopharma
- Requires innovative strategies and solutions
- Strong tailwinds supporting this segment
- Robust market, expecting continued growth •





View from a research analyst

Gareth Evans Progressive Equity Research





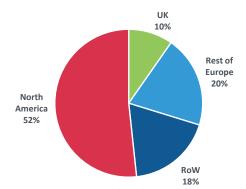
Investor wish list		Comment		
Large and growing market	√√?	Life sciences spends a lot on technology – COVID-19 may accelerate this		
Defensible position with barriers to entry		Multi-decade history with market-leading software in many areas		
Strong margins, cash generation and dividends		Good levels of margins and cash; currently being reinvested		
Positioned for acquisitive growth		Many deals over many years – larger and more frequent recently		
Meets ESG criteria – and "goes beyond"		Well-managed group with strong adherence to various criteria		
Credible and strategic management team	~ ~ ~	Good level of knowledge and experience; "strength in depth" across team		



Multi-year performance







Date Mar 2021	Acquiree d-Wise Technologies	Business area Clinical trial technology and consulting solutions	(£m) 22.5
Mar 2021	The Edge	Discovery software	8.5
Nov 2019	Leadscope	Safety assessment software	3.6
Sep 2016	Notocord	Pre-clinical Safety Pharmacology software	3.5
Jun 2016	Samarind	Regulatory Information Management software	2.5
Nov 2013	Perceptive Instruments	In vitro study data collection and study management for genetic toxicology	1.3
May 2013	Logos	Electronic data capture software	5.0
Mar 2011	Biowisdom	Data sharing and data mining software	1.5



Sales & profit, global reach and M&A

Consideration



Valuation expanded recently on delivery and acquisition-led increase in market cap and overall scale

Software companies can (and do) often trade on higher multiples

	Market Cap	EV/Sales		EV/EBITDA	
Name		2021	2022	2021	2022
Sage Group PLC	7,357	4.0	3.8	17.4	16.1
Blue Prism Group PLC	788	3.7	3.1	n/a	n/a
AVEVA Group PLC	11,137	10.4	8.9	32.1	26.2
Craneware PLC	712	12.3	11.5	36.5	34.7
accesso Technology Group PLC	244	3.5	2.8	n/a	n/a
Sopheon PLC	89	3.3	3.0	24.4	22.2
Beeks Financial Cloud Group PLC	69	5.2	4.3	15.8	12.6
Cerillion PLC	254	9.5	8.4	28.9	24.5
EMIS Group PLC	731	4.2	4.0	13.8	12.9
GetBusy PLC	43	2.8	2.6	n/a	n/a
Idox PLC	295	4.4	4.2	14.6	13.0
Tribal Group PLC	210	2.6	2.5	13.1	12.7
Average ex Instem		5.5	4.9	21.8	19.4
Instem PLC	162	3.0	2.5	15.9	12.1



Scale and success tend to drive higher multiples



Thank you

Gareth Evans







+ + + + + + + + + + + +

SUMMARY Phil Reason



Summary

- Positive structural drivers and regulatory regime stimulating growth for our products and services
- Highly resilient business model
- Large client base with high levels of recurring revenue
- Increasing abilities to cross sell to existing and new clients
- Increasing SaaS delivery, improving margins and quality of earnings
- Well placed to continue to augment strong organic growth with highly complementary acquisitions

Positive Market, Industry and Company Trends







THANK YOU

instem.com

- We appreciate your time & support
- A recording of today will be made available
- We will respond to any unanswered questions after the event

info@instem.com