

Xelay Acumen Introduction

Presentation Document
9/2025



Why Xelay Acumen?

Case Studies

Services and Workstreams

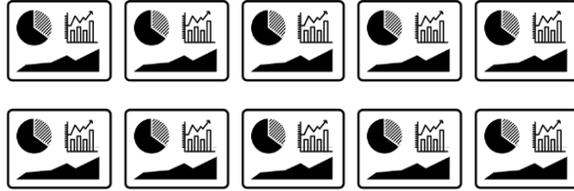
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Xelay Acumen Has Expertise in Analyzing, Interpreting, and Communicating Scientific/Medical Concepts & Therapeutics

Xelay Acumen Overview

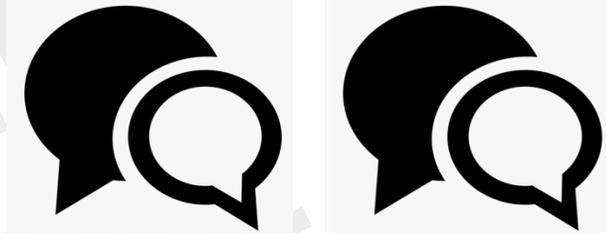
>100



Years of Medical Insights/ Analytics Expertise

visualizing and communicating compelling narratives/messages to realize potential value

>60



Scientific Platforms

for pharmaceutical therapeutics to organize and align communications

>50



Professionals

across medical/clinical sciences, commercial, **data analytics**, **biostatistics**, medical writing, publication, event planning, client services, project management, consulting, and SMEs¹

Global Support

around-the-clock
graphics and data
analytics



SF Bay Area



Taipei

Converting Challenges to Opportunities: Xelay Acumen Approach

Medical Data Analytics

Identify key compelling differentiating and core clinical attributes to highlight to scientific, commercial, and investor audiences. Driver for evidence generation and data visualization

Scientific Platform

Define the concise compelling narrative to consistently communicate the unmet need and how the therapeutic candidate delivers against that unmet need. Become aspirational for publications, CME, scientific & investor communications

Publications

Across medical congresses and peer-reviewed journals, establish unmet need while simultaneously communicating the therapeutic candidate's compelling preclinical & clinical results

KOL Engagement & Advocacy

Rapidly cultivate quality KOL relationships in medical practice, congress leadership, & academia, to advocate for the therapeutic candidate. These may include 1:1 meetings, advisory boards, speaker programs, education support, and other communication and dissemination

Congresses

Establish your Company's presence and commitment to patients and health care providers while strengthening advocacy across KOLs, professional societies, & guidelines committees

Relevant Xelay Experience and Expertise

Development

- 60+ products developed spanning marketing & medical affairs
- Current and recent engagements include creating and leading entire market preparation, commercial, and medical affairs department for highly successful development products

Data Analytics

- Create and lead Medical Data Analytics for multiple biotech/pharma organizations
- Analyze clinical data with scientific rigor and an understanding of commercial opportunities and impact

Med Comm

- Leverage scientific and clinical data to credibly emphasize importance of key attributes
- Redefine and shape pre-launch markets to disproportionately favor one product over another
- Clear and concise communication of new mechanisms and innovative products to scientific, medical, and financial audiences

Relationships

- Successful track record of establishing deep relationships amongst KOLs, national account organizations, professional/medical societies, patient advocacy groups, government agencies, and nurse staff

Xelay Acumen Operates as Part of the Internal Organization and Collaborates Across Departments

Clinical

- SAP strategy
- Post-hoc analyses
- Research recommendations that target differentiation

Regulatory

- NDA Submission
- Label Strategy
- Alignment with Scientific Platform in submission documents (i.e. unmet need, product attributes, etc)

Commercial

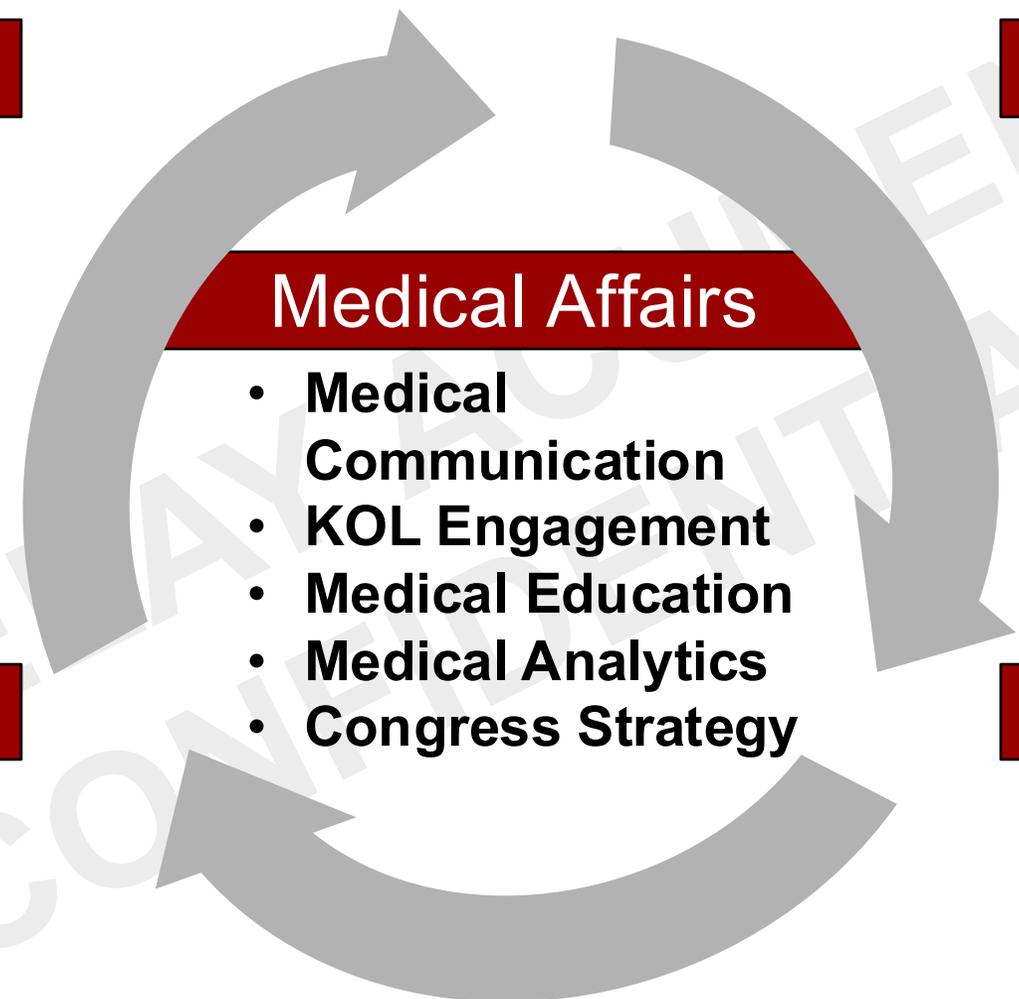
- Alignment on Scientific Platform & Narrative
- Publications Planning
- Investor Presentations

Medical Affairs

- Medical Communication
- KOL Engagement
- Medical Education
- Medical Analytics
- Congress Strategy

Corporate Dev.

- Investor Presentations
- Fundraising Support



Xelay Acumen Is Poised to Support Development Activities to Strategically Optimize Value

Expertise

In addition to a long track record of success, specific experiences that represent best-in-class successes in market preparation, commercialization, and medical affairs development activities include Speaker Programs, Marketing Plans, Medical Data Analytics, Competitors Medical Differentiation, Medical Communications (publications, advisory boards, KOL cultivation), Preclinical, Phase I, II, III and IV trials, Observational Data and Health Economics and Outcomes Research, Congress Strategy and Medical Education

Focus

Thought partner to prioritize which projects and activities lead to differentiating high-value impact in a short timeframe

Value

Because of our specific expertise in market preparation, commercialization, and medical affairs support of clinical development candidates and our focus on high-impact value realization, Xelay Acumen will provide support to achieve ***more, faster, and at a lower cost***

Additionally, Xelay Serves as Senior Management Support

Management

Senior management and support of ongoing workstreams

External Facing

Represent your Company to externally facing stakeholders including KOLs, GPOs, professional associations, payors, government agencies, partners, and advocacy groups

Resource

- Extend your Company's senior management bandwidth
- Provide advice and guidance broadly on commercial and scientific communication strategy and implementation

Why Xelay Acumen?

Case Studies

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Case Study A – ZS Pharma, Inc

SITUATION

- ZS Pharma is a small pharmaceutical company that was founded in 2008 with a single product in their pipeline for the treatment of hyperkalemia
- ZS just completed phase 2 trials, with promising results
- ZS Pharma had done no outreach to the scientific or medical communities

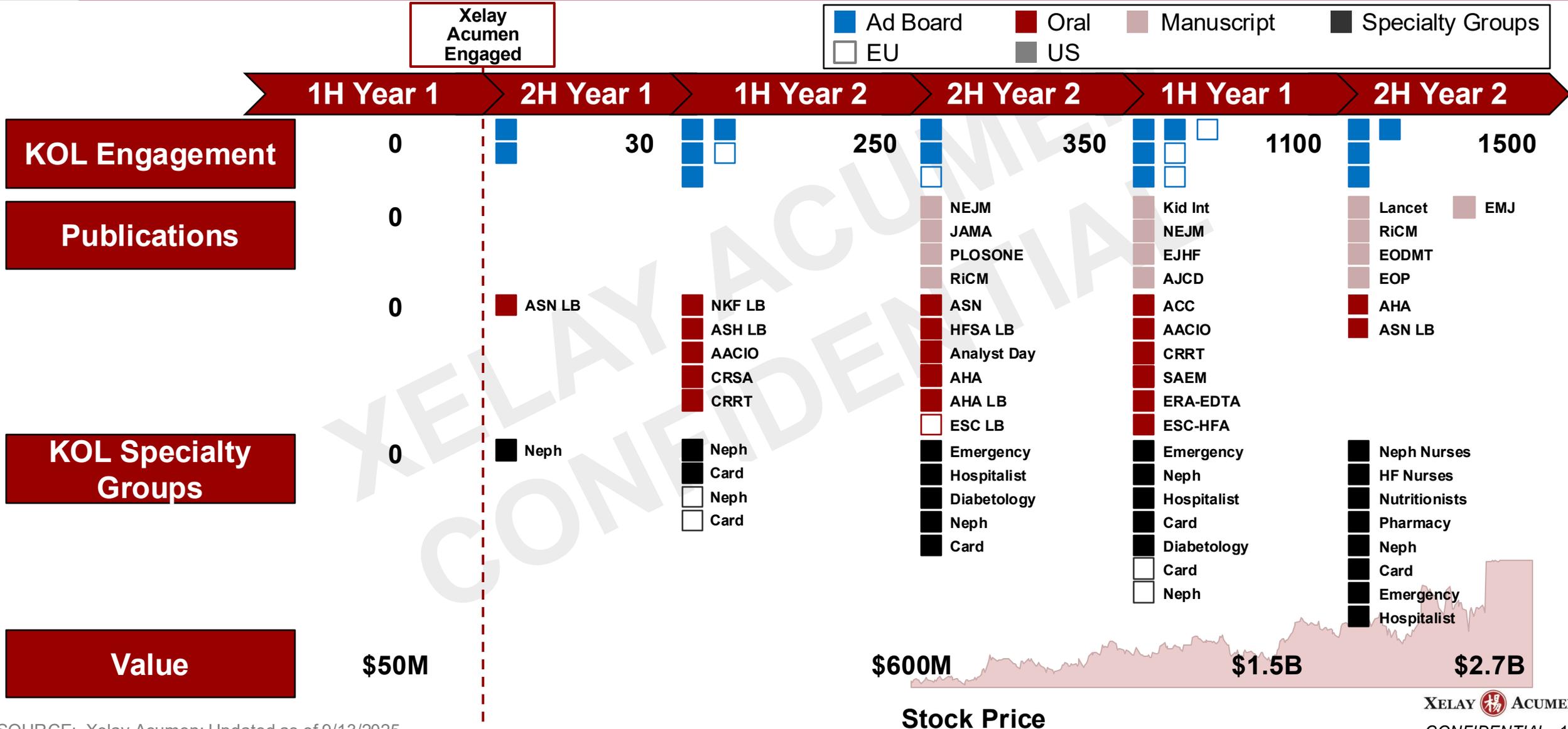
CHALLENGE

- Hyperkalemia was not a main focus of medical or scientific community and guidelines are unclear or inconsistent
- Two hyperkalemia products already on market
- Two competitors in development have completed all trials while ZS has just finished their first Phase 2 trial
- Unclear how ZS's product could differentiate or compete in a crowded market

RESOLUTION

- Prioritized market preparation and commercial medical affairs as strategic functions of ZS Pharma
- Engaged Xelay Acumen to rapidly build a commercial and medical affairs department from scratch and develop and execute a winning strategy
- As a result, their product has become known as a novel therapy, differentiated by selectivity and MOA, and was acquired for \$2.7B

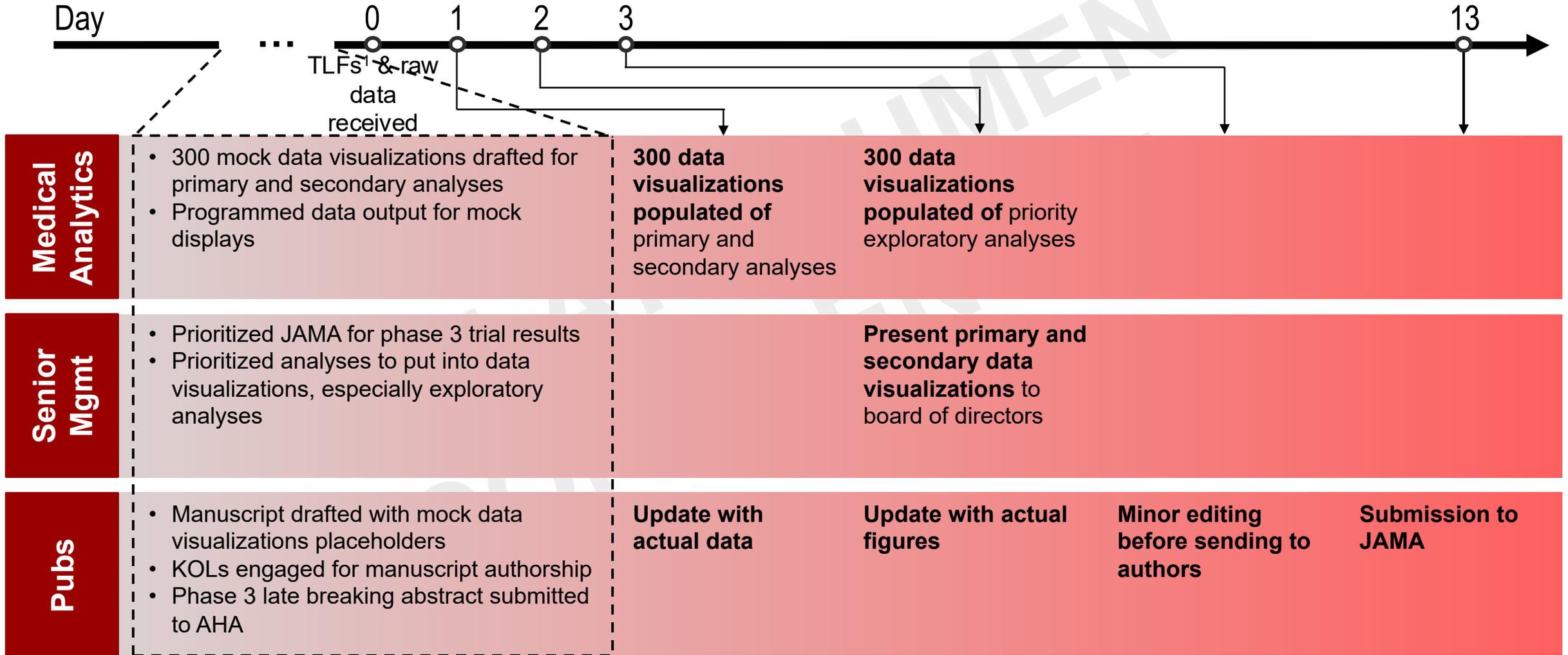
Case Study A – Prioritizing Market Prep & Commercial Med Affairs as Strategic Functions, Xelay Acumen Increased ZS Pharma’s Value



SOURCE: Xelay Acumen; Updated as of 9/13/2025

Case Study B – JAMA: Enabling Rapid Submission of Publication to Preeminent Journal in <2 Weeks of Data Receipt

Timeline of Strategic Phase 3 Clinical Trial Publication Submission: JAMA Manuscript



¹ Tables, listings, and figures

Case Study B – 4 Months from Primary Clinical Trial Completion Date to Publication in JAMA

ClinicalTrials.gov

A service of the U.S. National Institutes of Health

Try our beta test site

Safety & Efficacy of Zirconium Silicate Dosed for 28 Days in Hyperkalemia.

This study has been completed.

Sponsor:
ZS Pharma, Inc.

Enrollment: 258
Study Start Date: March 2014
Study Completion Date: January 2015
Primary Completion Date: August 2014 (Final data collection date for primary outcome measure)

4 Months

December 3, 2014

Effect of Sodium Zirconium Cyclosilicate on Potassium Lowering for 28 Days Among Outpatients With Hyperkalemia

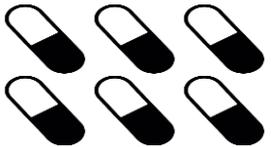
The HARMONIZE Randomized Clinical Trial

Mikhail Kosiborod, MD^{1,2}; Henrik S. Rasmussen, MD, PhD³; Philip Lavin, PhD⁴; et al

» Author Affiliations | Article Information

Case Study C – Established a Publications Plan, Compliant Review Process, Scientific Messaging, & KOL Strategy

Xelay Medical Affairs Scope of Support in 1 Calendar Year

Integrated Strategic Publication Plan			Compliant Publication Review Process	
<p>6</p>  <p>Therapy Candidates</p>	<p>70+</p>  <p>Congresses Prioritized</p>	<p>44</p>  <p>Publications Planned</p>	<p>~450</p>  <p>PRC¹ & Author Approvals After Rounds of Reviews to Ensure</p> <ul style="list-style-type: none"> • Authorship Contribution and Compliance • Accurate and On-Time Submission 	
Consistent Scientific Messaging			Initiated KOL Engagement Strategy	
<p>600+</p>  <p>Literature Scanned</p>	<p>80+</p>  <p>Literature Synthesized</p>	<p>100+</p>  <p>Statements Sourced</p>	<p>600+</p>  <p>KOLs Researched</p>	<p>9</p>  <p>Plan of Actions Developed</p>

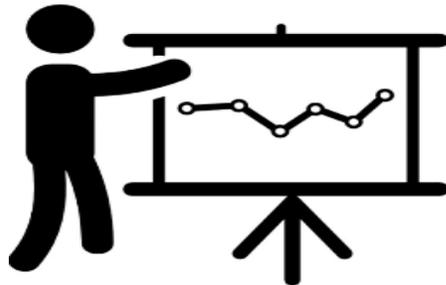
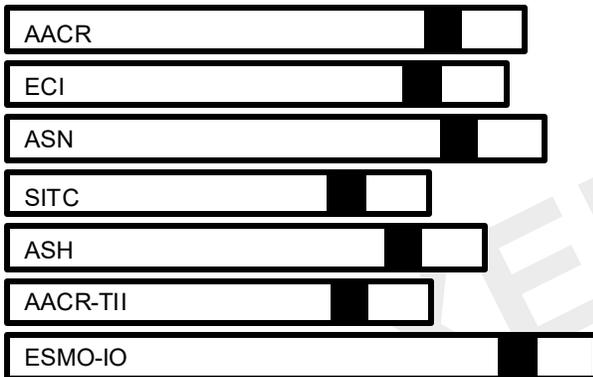
¹ Publications Review Committee

...Which Resulted in 22 Publications in Under ~7 Months

Publications Overview Across Programs Number of Publications

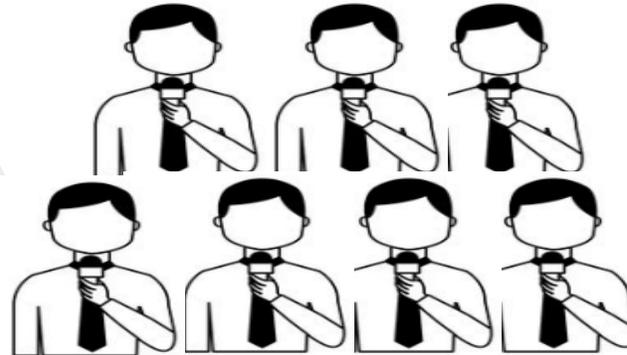
ABSTRACTS & POSTERS

13 Abstracts accepted at 7 conferences as posters



ORAL PRESENTATIONS¹

7 Rapid orals or invited talks



MANUSCRIPTS

2 Manuscripts accepted



¹ Publications Review Committee

Introduction to Xelay Acumen
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Selected Med Affairs and Commercial Workstreams

Medical Data Analytics & Visualization
Scientific Platform, Claims Matrix, & Gap Analysis
Literature Library, Literature Scan & Synthesis
Publications
KOL Engagement and Advocacy
Advisory Council Strategy
Congress/Conferences Strategy
Medical Information
Medical Education Strategy
Training
Health Economics Outcomes Research

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Please complete this form (click [link here](#)) to schedule an introductory call so we can better understand your company's needs and explore how Xelay Acumen can support you

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