

Strategic Sourcing: Building Consistent, Quality Partnerships in Pharma

Focus on Regulatory Affairs & Drug Safety

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Objectives

- Fit of **vendor management** in the **Global Regulatory Affairs and Drug Safety (GRADS)** organization at Jazz Pharma
- Remit of the **GRADS Alliance Management (GRADS AM)** organization in managing **accountability and performance** of vendors and business partners
- Specific **responsibilities** of GRADS AM groups in maintaining **patient safety and regulatory compliance**
- **Scenarios and examples** of interactions with stakeholders and vendors for improved **quality and cost control**



Jazz Pharmaceuticals is a global company with strong emphasis on rare disease therapies in oncology and neuroscience

Example Commercial Products

Oncology

 **ZIIHERA**[®]
(zanidatamab-hrii)

Potential to be the therapy of choice in multiple HER2+ tumors

 **ZEPZELCA**[™]
(lurbinectedin)

Leading treatment for 2L ES-SCLC¹; expansion opportunity in 1L ES-SCLC

 **RYLAZE**[®]
asparaginase erwinia chrysanthemi
(recombinant)-rywn for injection 10mg/10.5mL per vial

Standard of care in pediatric ALL/LBL patients with asparaginase HSR reaction

Neuroscience

 **Epidiolex**[®]

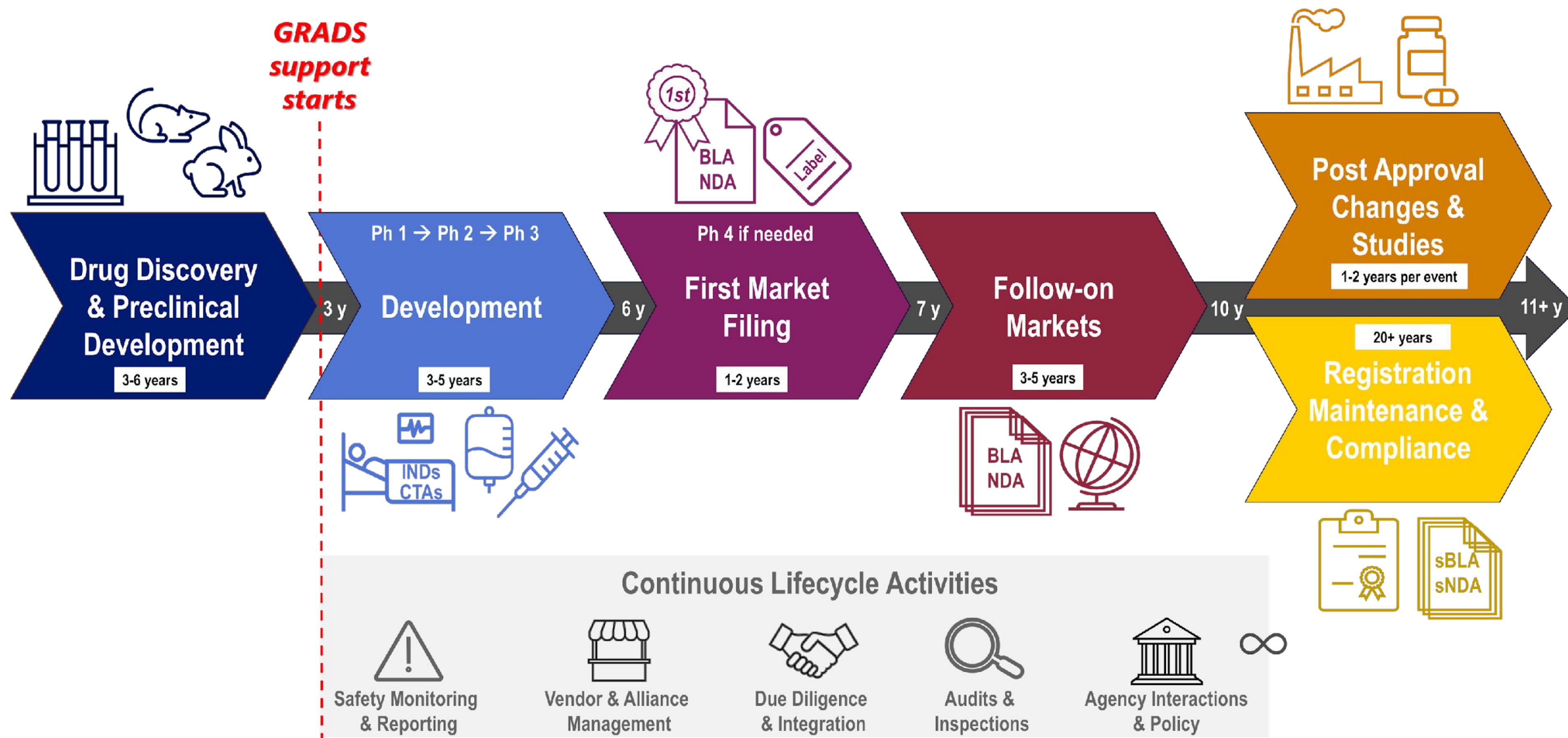
#1 branded treatment for epilepsy²

xywav[™] 

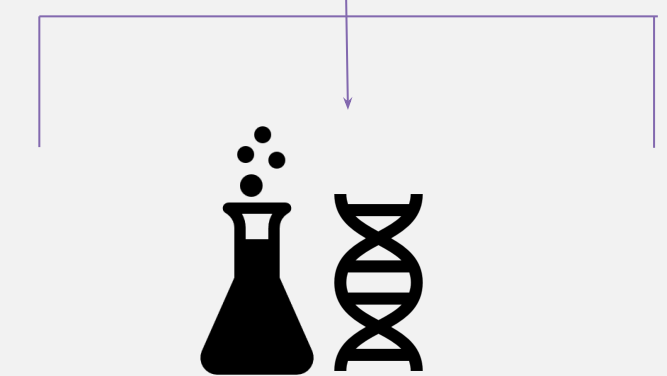
#1 branded treatment for narcolepsy² and only approved IH therapy



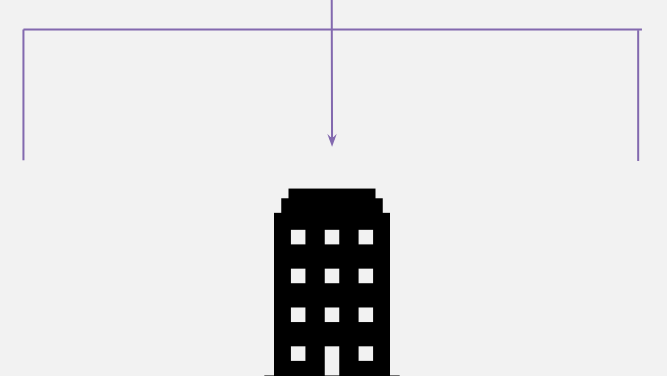
GRADS Contributes Across the Full Drug Development Lifecycle



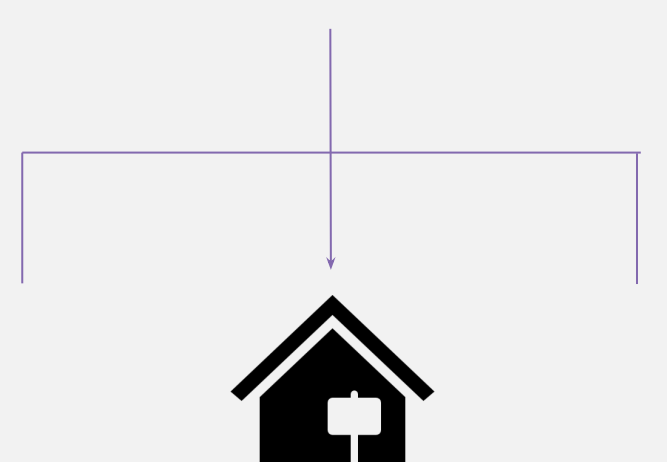
Jazz Pharma is a global company with several divisions



Research & Development division has multiple organizations



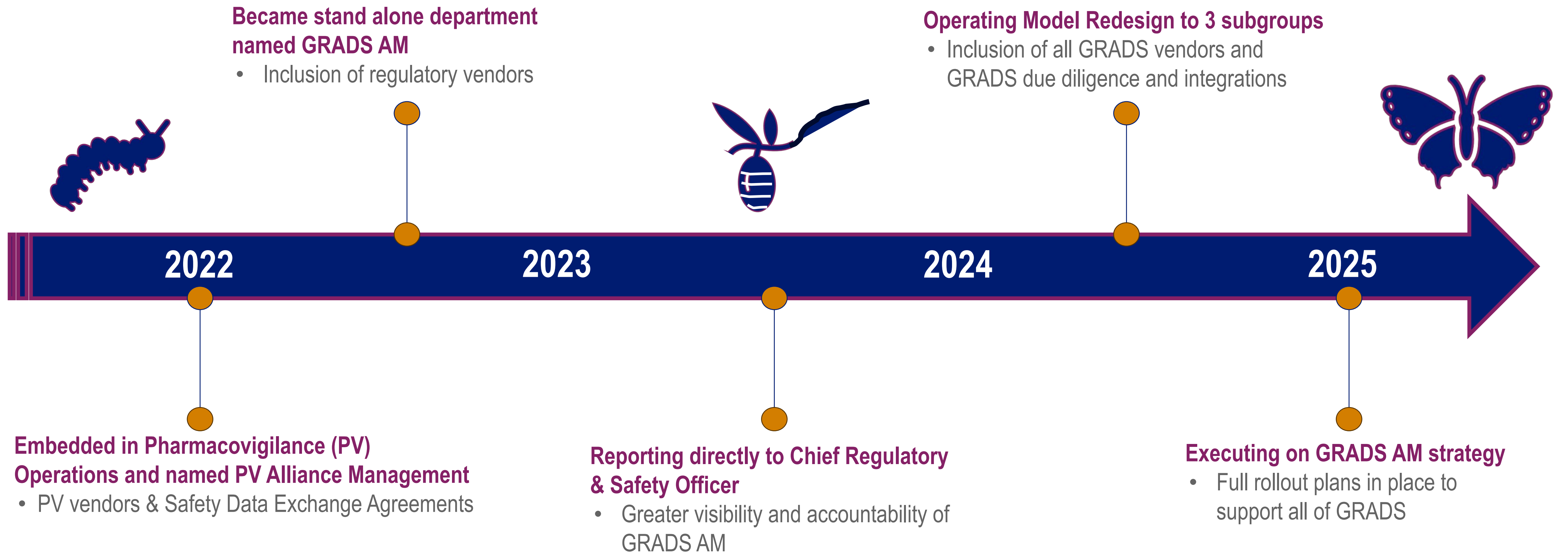
GRADS organization has various departments



GRADS Alliance Management department



Evolution of GRADS Alliance Management



...from PV operations focus to whole GRADS remit

GRADS AM: driving excellence in vendor and business partner management and deal executions



Business Partnership Operations (BPO)

GRADS critical-to-success factors for due diligences in deal evaluations and effective execution on integrations



Pharmacovigilance Alliance Management (PVAM)

Safety commitments for indirect-to-GRADS vendors and business partner agreements



Strategic Sourcing & Vendor Management (SSVM)

GRADS resource capacity through effective oversight and management of vendor relationships



SSVM procedures and responsibilities critical for successful GRADS vendor management



- Selection, Management, & Oversight of Service Providers
- Approved Service Provider Lists

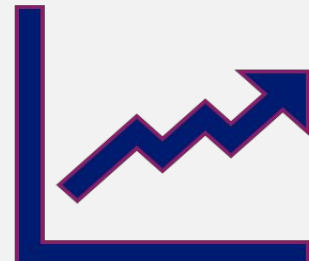



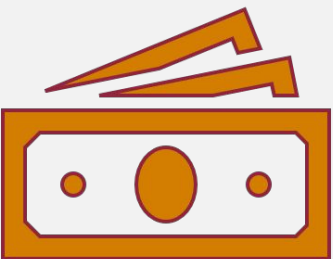
- Master Services Agreements (MSA), Statement of Work
- Service Provider Oversight Plans (SPOP)
- Governance & Escalation

- Contract storage
- Financial management
- GXP recordkeeping

- Audits by and of every GRADS vendor
- Oversight of vendors in inspections

- Strong relationships building
- Effective communication and negotiation skills

Scenario 1: Stakeholder collaboration for increased quality & cost savings

 <p>Cost v Time</p>	<ul style="list-style-type: none"> • Cost increases: Each year, vendor increased headcount for Adverse Event (AE) reporting to handle increasing report volumes. 	
	<ul style="list-style-type: none"> • Root cause: SSVM and PV Operations solutioned with vendor to achieve 41% reduction in misreporting in 1 year, thus needing less vendor touch time (headcount). 	 <p>Errors v Time</p>
 <p>Metrics Analysis</p>	<ul style="list-style-type: none"> • Oversight: SSVM assessed vendor performance metrics and estimated a reduction of 8 headcount should be reflected to align with reduced vendor touch time. 	
	<ul style="list-style-type: none"> • Procurement: Led negotiations resulting in agreement by vendor to remove 5 headcount and revise invoices for underutilization of headcount in prior months. 	 <p>Negotiation</p>
 <p>Reduced Costs</p>	<ul style="list-style-type: none"> • Cost Savings: \$1.4 Million for 1 year, with potential for future savings. 	



Scenario 2: Lessons learned on vendor selection

Stakeholder Request	<ul style="list-style-type: none"> • Local literature monitoring and local QPPV service provider needed • SSVM meets all stakeholders together: QPPV office, PV Operations, Procurement
Prioritize Needs	<ul style="list-style-type: none"> • Clearly define requirements upfront; broad needs statements lead to churn and eventual delays to update with more specific requirements
Vendor Search	<ul style="list-style-type: none"> • Prescribe a clear timeframe for the RFI & RFP so stakeholders do not add vendors after the RFP is sent out
Vendor Selection	<ul style="list-style-type: none"> • Initiate relevant risk assessments and vendor qualification process with Quality team, and establish agreement/contract
Performance Assurance	<ul style="list-style-type: none"> • Define Key Performance Indicators and global & local regulatory requirements for vendor compliance, identify leading indicators of business risk, specify governance
Vendor Transition	<ul style="list-style-type: none"> • Provide sufficient vendor overlap period for file, knowledge, and systems transfers • Site visit for kick-off of new vendor relationship

PVAM provides risk-based safety reporting obligations for non-GRADS vendors

- Regulatory requirements mandate **AE reporting** rules for pharma
- AE reporting obligation extends to **non-GRADS vendors**; examples:
 - Market Research vendors
 - Specialty Pharmacies
- PVAM assesses and provides **proper risk-based reporting obligations** for non-GRADS vendors

Continuous Process (SOP) Improvement

Project	Improvement	Impact
Industry Standard 	AE reporting timeframe changed from stringent 1 calendar day to 1 business day and no more than 3 calendar days	Rapidly resolved 6 contract negotiations that were open for 2 years with more flexible, industry standard AE reporting timeframe
Cycle Time Reduction 	Transfer of Market Research material review from PV Operations to Market Research project lead	Resulted in process cycle time reduction of 124 h annually by placing task with more appropriate team

PVAM establishes Safety Data Exchange Agreements (SDEAs) with Jazz business partners

- While business partners are not vendors, transactions are essential for **patient safety and regulatory compliance**
- SDEAs specify **business partner obligations** to ensure regulatory compliance
- Regulations require the ability to **demonstrate compliant exchanges** which are checked in audits and inspections



BPO evaluates new business opportunities with a GRADS lens for regulatory and safety fit

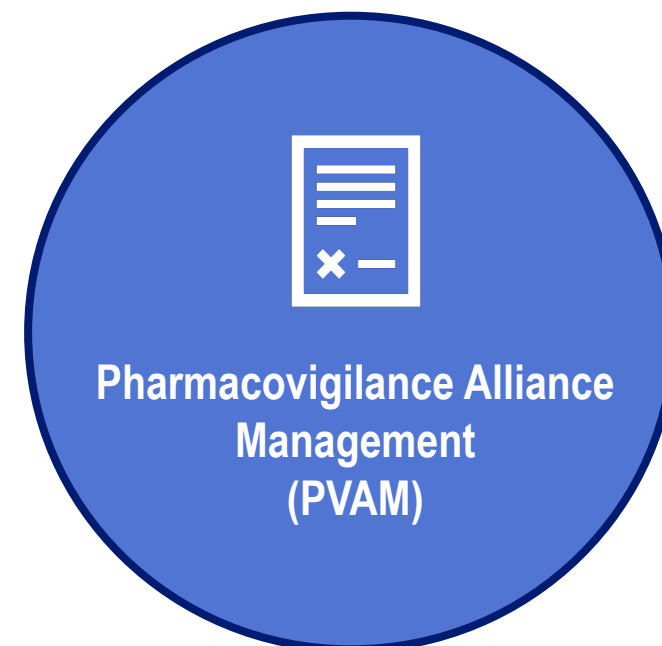


- Search and Evaluation and Corporate Development engage BPO for GRADS input on near final **deal assessments**
- BPO leads GRADS **due diligences**, driving consistency and completeness through use of a work instruction and GRADS specific checklists



- If a deal is signed, BPO leads **integration** of this asset for the GRADS organization according to SOP

Key Takeaway Points



- GRADS AM is comprised of 3 groups which drive accountability and compliance across **vendor management, business partner management, and evaluation and integration of new assets.**
- Each group has robust processes that are followed to ensure **consistency and high performance.**
- Each group **collaborates both internally and externally** to deliver the **highest quality with most compliant delivery** and strives for continuous improvement and utilization of technology to improve efficiency.



Thank you

Questions and comments, please.