



The Ugly Truth about Payers and PAMA: What Labs Can Expect and How to Respond

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Executive War College — May 1, 2019



How Did We Get Here and Did PAMA Produce Market Pricing?

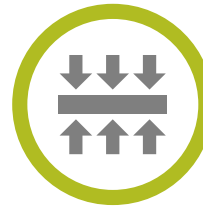
- Congress imposed across the board reductions to pay for SGR
- CMS proposed further reductions to reflect “Technical Adjustments”

- 75% of codes on CLFS decreased;10% increased
- Elimination of ATP payment provides increase in AMCC tests
- Revised OIG impact estimate up >72%

In 2014



Industry Impact



Historical Rates

- Based on lab charges in 1984–1985, adjusted annually for inflation
- 57 local fee schedules

PAMA

- No cuts 2014-2017
- Reductions capped at 10% each year 2018-2020
- Repeal CMS authority for “Technical Adjustment” cuts

What's Next?

- Fiscal leadership = insight on contractual process reviews and reimbursement due diligence
- Operational Efficiency
- *GAO Report on AMCC unbundling*
- Second PAMA data collection period underway

Stay up-to-date on PAMA: <https://www.xifin.com/pamahq>

CMS Publishes Changes to PAMA Reporting in Final PFS Rule

Expansion in number of reporting labs – Smaller Labs and Hospital Labs

Expect more:

- ✓ Independent Labs
- ✓ Outreach Hospital Labs

CMS responds to comments and indicates final rule will apply to 2019 data collection period

Applicable Lab definition has the most significant impact and will include most hospital labs in the next data collection period – First Half of 2019

PUBLISHED CHANGES TO THRESHOLDS

Majority of Medicare revenues threshold

- New calculation methodology (excludes Part C from total)
- CMS suggests that 43% more labs may be included in the “applicable lab”

Low expenditure threshold

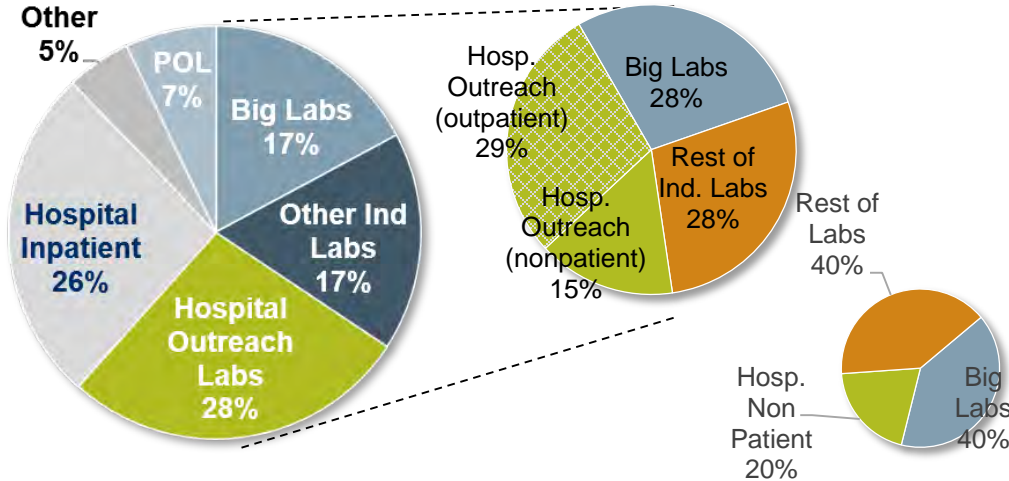
- Proposed changes to \$12,500 collection period revenue
- CMS received comments on impact of both lowering (to \$6,500) and increasing (to \$18,750) threshold
- No changes will be made

NPI definition of applicable lab

- CMS will identify “applicable lab” using Form CMS-1450 14x bill type vs. NPI
- This will effectively include all hospital labs meeting the low expenditure threshold

Impact of Revised Guidance on Hospital Lab PAMA Reporting

Proportion of Total Lab Market



Lab Type	% of Tot	Weighted Avg Impact	% of Tot	Weighted Avg Impact
Big Labs	28%	(44.8%)*	40%	(17.9%)*
Rest of Ind. Labs	28%	8.0%*	40%	3.2%*
Hosp. Outreach Labs	44%	32.1%*	20%	6.4%*
Total	100%	3.8%	100%	(8.3%)*

*Source: XIFIN analysis based on XIFIN PAMA data set

Volume of Data Reporting Impacted

AHA and hospitals push back on PAMA reporting

- Hospitals lack financial systems to gather PAMA data
- Hospitals unable to ID non-patient vs. outpatient

2/27/19 CMS issues guidance

- Guidance provided subsequent to collection period
- Confirms nearly all hospital outreach labs must report
- Clarifies only report NON-PATIENT data
 - Potential impact to data previously submitted
 - Significantly reduces data reported by newly qualified outreach labs

Hospital labs must only report “non-patient”

- Arbitrary guideline limits volume of reportable data
- Additional data is not likely to be of a magnitude that changes “average median”
- 35% of outreach is non-patient, 65% is outpatient

Private Payor Pricing Erosion in 2018

- Average Allowed for Private Payors Decreased from 2017 to YTD 2018

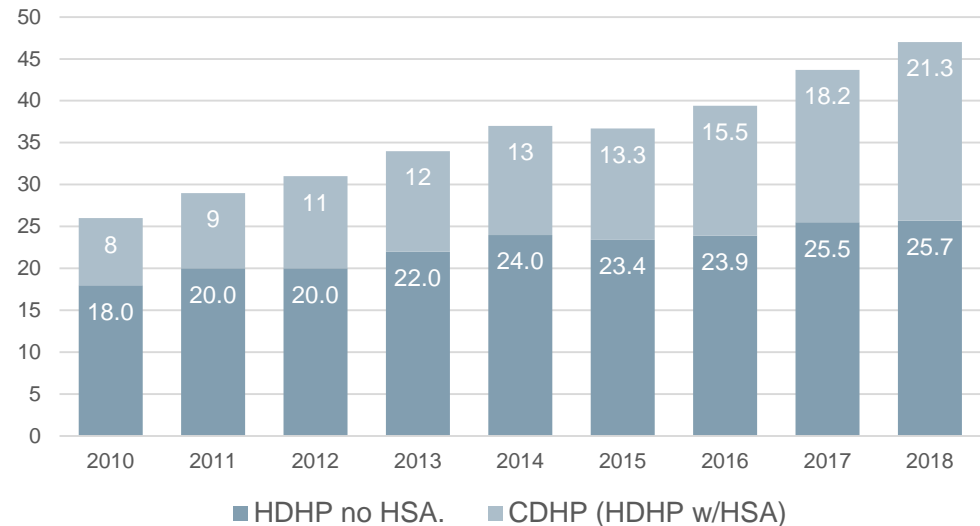
- Hospital -3.5%
- Independent -2.9%

- Trends

- Aetna, Cigna, Blues, UHC offering 20-25% below 2018 Medicare rates
- Multiplan cutting their fee schedule in half in some regions
- Increasing number of beneficiaries in high deductible health plans

% of Privately Insured Persons Under 65 Enrolled in High-deductible Health Plans

2010 - March 2018



Percentage of persons under age 65 enrolled in a high-deductible health plan without a health savings account or in a consumer-directed health plan, among those with private health insurance coverage. CDHP is consumer-directed health plan, which is a high-deductible health plan (HDHP) with a health savings account (HSA). HDHP no HSA is a high-deductible health plan without an HSA. Source: NCHS, National Health Interview Survey

Post PAMA Erosion of Commercial Pricing

Codes	Medicare				Commercial			
	2017	2018	2019	2020	2017	Q4 2018	% Change	PAMA Median
84443	\$23.05	\$ 20.75	\$ 18.67	\$ 16.80	\$15.42	\$13.82	-10%	\$14.87
G0480	\$117.65	\$ 114.43	\$ 114.43	\$ 114.43	\$98.97	\$ 90.97	-8%	\$47.96
80061	NA	\$ 16.53	\$ 14.88	\$ 11.23	\$11.17	\$ 9.92	-11%	\$11.23
80053	\$14.49	\$ 13.04	\$ 11.74	\$ 10.56	\$ 8.75	\$ 8.33	-5%	\$9.08
85025	\$10.66	\$ 9.59	\$ 8.63	\$ 7.77	\$ 6.48	\$ 5.90	-9%	\$6.88
82306	\$40.61	\$ 36.55	\$ 32.89	\$ 29.60	\$26.37	\$ 23.08	-12%	\$26.37

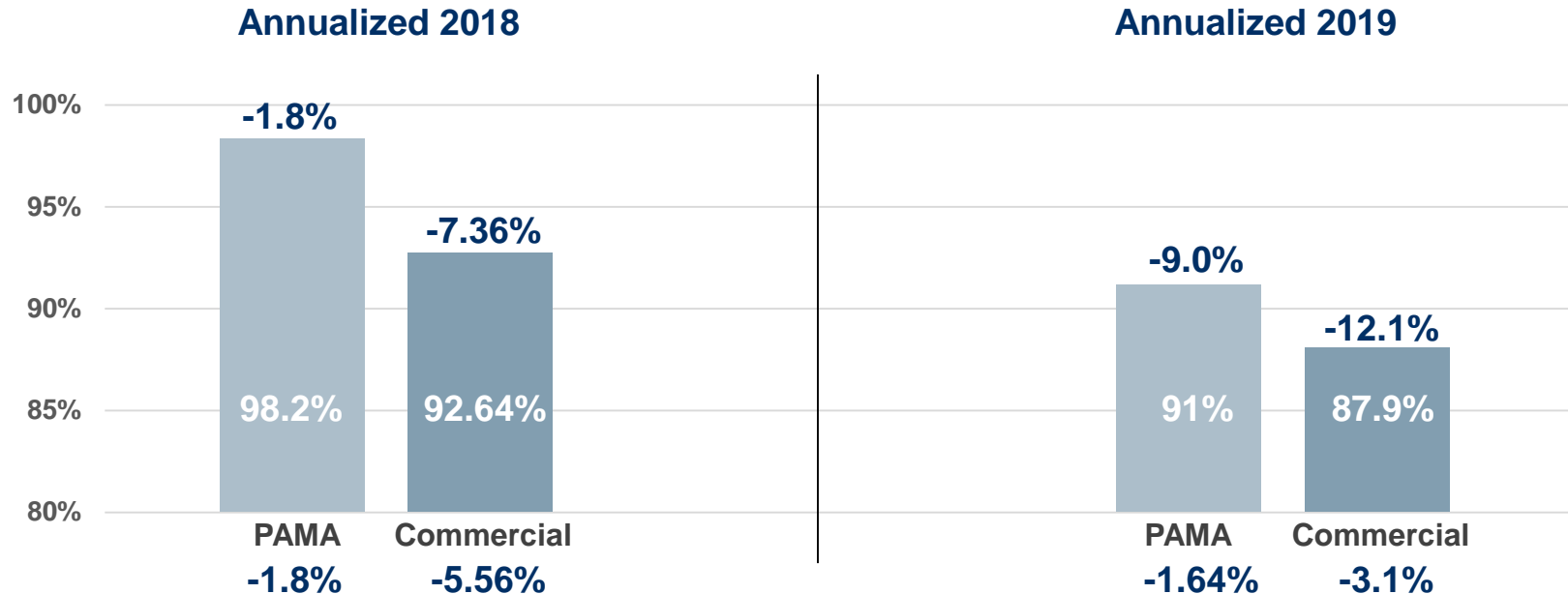
Tox G Codes	Medicare				Commercial			
	2017	2018	2019	2020	2017	Q4 2018	% Change	Q1 2019
G0480	\$117.65	\$ 114.43	\$ 114.43	\$ 114.43	\$98.97	\$ 90.97	-8%	\$87.98
G0481	\$160.99	\$ 156.59	\$ 156.59	\$ 156.59	\$114.88	\$ 110.64	-4%	\$108.25
G0482	\$204.34	\$ 198.74	\$ 198.74	\$ 198.74	\$133.06	\$ 132.59	0%	\$129.18
G0483	\$253.87	\$ 246.92	\$ 246.92	\$ 246.92	\$171.82	\$ 170.76	-1%	\$170.08

Molecular IS now seeing a negative impact for non-proprietary testing

Commercial Molecular	2017 vs Q4 2018
Infectious Disease	↓ 3.60%
Germline Testing	0%
Somatic Testing	↓ 2.10%
Prenatal	↓ 1.20%

Is The Rate Of Decay Equal Across Payor Types?

The majority of losses stem from both Medicare payments as well as Commercial groups, especially those payors who have a larger contractual exposure to Medicare fee schedule rates



Trends Specific by Speciality

Based on all XIFIN Cross Customer Data



Cardiovascular Disease

54.6% increase in prior auth related denials

Past 24 Months



Oncology Imaging and Diagnostics

72.8% increase in prior auth related denials

Past 24 Months



Women's Health

62.1% increase in prior auth related denials

Past 24 Months

40% of PAs abandon due to complex approval policies

Second round of PAMA may cut individual test payment rates by up to

15%

Solid reporting from labs is the key to mitigate future price cuts

- ✓ Report on actual allowables vs. payments
- ✓ Validate accuracy of payments
- ✓ Optimize appeals activity to avoid reporting under payments

REPORTING

- PAMA statute allows penalties of \$10K/day for each failure to report, error in reporting or omission in reporting applicable information.
- Correct contracting problems prior to reporting period
 - Eliminate coupled contracts
 - Evaluate fees for each CPT to determine outliers that need to be re-negotiated
- Establish financial systems with appropriate reporting capabilities and retain source documents

Strategies for Labs to Offset PAMA Impact



Cost reduction efforts

- Workflow automation to remove clerical decision making and achieve labor efficiencies
- Reduce total cost of billing to below 4% while achieving bad debt targets



Diversify testing menu and expand specialty testing



Private Payor contract negotiations

- Leverage hospital to negotiate better lab pricing
- Leverage regional presence and value based pricing concepts

5-20% POTENTIAL A/R COLLECTIONS

Update technology infrastructure

- ✓ Web based systems - WS integration capabilities for real time bi-directional connectivity
- ✓ “Service based architecture” that allows functionality to be used at point of need

Select accounting based billing software

- ✓ Financial integrity (GAAP, SOX compliant)
- ✓ Referential integrity
- ✓ Deep analytics

Patient engagement automation

- ✓ Up-front patient estimation and prepayment
- ✓ Patient portal, IVR, Electronic secondary insurance filing

Payer Contract Negotiation Tips



De-couple payor specific fees from current Medicare CLFS

- Preferably should also not be tied to a prior year's static CLFS
- Best to have a CPT based FS closely related to cost
- A percentage of charge master is the only way to establish market pricing



Determine cost of performing each test or use RVUs to create the lab's charge master

- Create a relative FS that reflects a rational relationship to the cost and value of the test
- Validate that billed charges are not lower than any payor's contracted rates



Determine and align CPT codes by revenue volume for your lab

- Negotiate top tests representing the highest revenue impact to your lab
- Make sure none of the remaining procedure codes are below cost



Determine the needs of the payor

- Network coverage, patient convenience
- Payors need actionable data to demonstrate appropriate usage and quality
- Payors desire optimized lab utilization that delivers healthcare savings



Other contract provisions to negotiate

- Filing deadlines of 180 days
- Term and termination: Negotiate long term, evergreen, with 120 days termination for convenience

Evolving Market Trends

Reimbursement Changes Shift Segment Focus

Clinical Lab	Physician Office Lab	Molecular Diagnostics	Hospital / Outreach	Pain Management & Device
<ul style="list-style-type: none"> Decline in number of labs offering full testing menus Growth in specialization (Pain, PGX, Cardiovascular, Genetic) Decline of rural labs with high Medicare/Medicaid mix and shift of business to hospital labs with higher routine testing margins Growth in esoteric reference testing labs and tighter partnership with hospitals Continued industry consolidation Independent labs pursue hospital JVs 	<ul style="list-style-type: none"> Shift of commodity testing to point of care with analyzer miniaturization & increased waived testing Physicians strive to achieve early diagnosis to manage chronic disease and hospitalization for quality reporting requirements Medicare's latest ACO regulations favoring doctor-led ACOs align labs that can deliver enriched data and analytics with those practices vs. physicians aligning with hospitals for integrated care 	<ul style="list-style-type: none"> Post PAMA pricing stabilizing bringing back investment to specialty genetic labs Specialty labs fighting to maximize specialty physician referrals Companion diagnostics drive therapeutic drug sales Data provides new revenue stream for labs and efficiencies for Pharma R&D Private payors managing coverage through Pre-Auth and Denials generating Appeals 	<ul style="list-style-type: none"> Hospital labs less impacted by PAMA cuts Health Systems focus on lab efficiencies: profit center vs. cost center Outreach business optimizes lab utilization Rural lab business shifts to higher margin hospital labs Creating complementary Reference Lab Partnerships Bringing lab, device & rad together 	<ul style="list-style-type: none"> Post PAMA pricing stabilized, but next reporting period may not PGX coverage advancing in 2018 Menu diversification extended to adjacent specialty areas, such as wound care Consolidation in market to drive economies of scale High demand created by opioid crisis Growing diagnostic Device Market New technology challenges for coverage & reimbursement

Technology needs to align with increasing segment needs

Deep Analytics

- Lab is an actionable data provider
- Value based pricing negotiations
- Data supports coverage/reimbursement
- Quality reporting

Infrastructure

- Technology Infrastructure
- Connectivity to facilitate clinical integration
- Scalability
- Operational efficiency

Financial Integrity

- Financial system
- GAAP/SOX/FASB
- Referential Integrity
- Business intelligence and analytics

Government Dynamics Affecting Lab Testing



Value Based Healthcare

Readmission Reduction

Hospital Acquired Condition Reduction

HEDIS**

MACRA & MIPS*

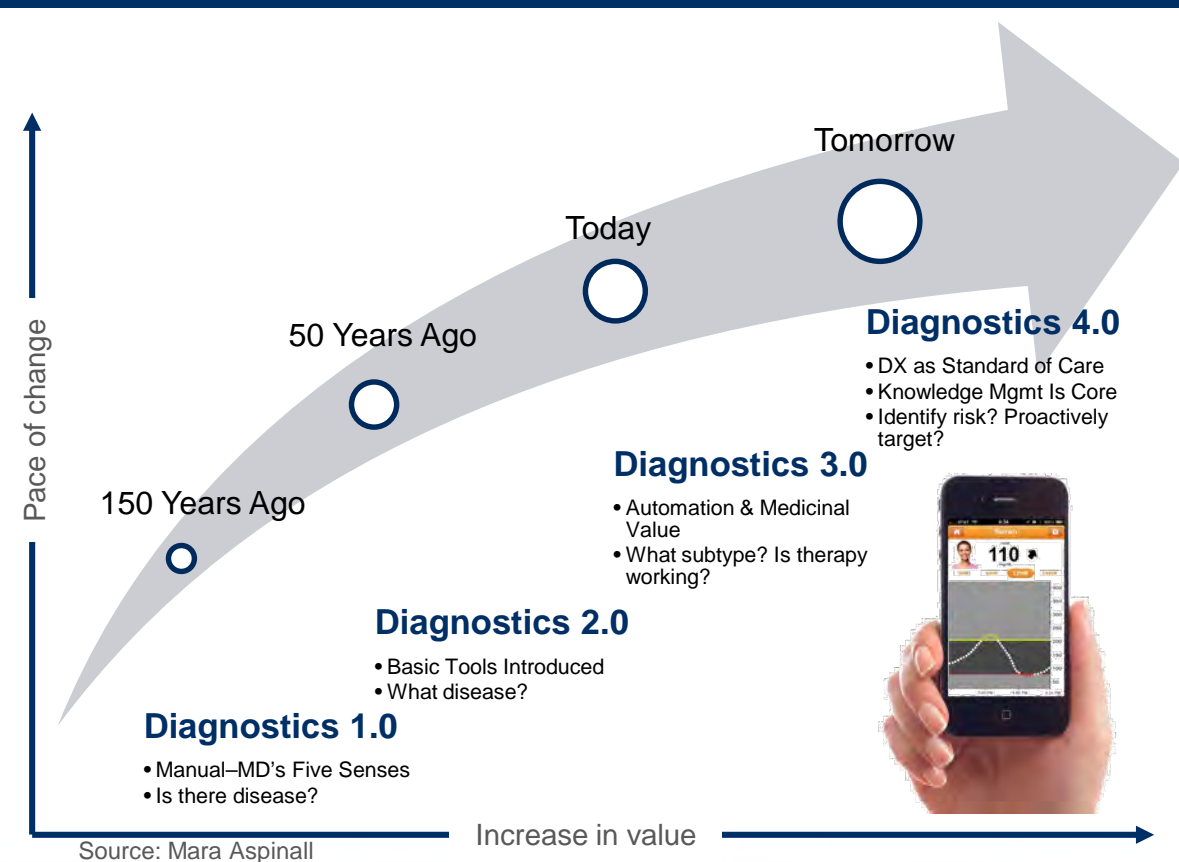
Affordable Care Act and ACO's (Hospital vs. Phys-led)

Protecting Access to Medicare Act (PAMA)

*Medicare Access and CHIP Reauthorization Act (MACRA) and Merit-Based Incentive Payment System (MIPS)

** Healthcare Effectiveness Data & Information Set (HEDIS)

The Evolution of Diagnostics: Climbing the Value Chain



Source: Mara Aspinall

Three necessary components

- Financial Data
- Clinical Data
- Business Intelligence / Analytics

Three elements that can change how medicine is practiced and optimize the economics of healthcare

- Clinical decision support tools
- Collaboration across MDTs
- Patient centered coordinated care

Laboratory's position of strength

- Diagnostics influence 70% of medical decisions & represent 80% of HER
- Rich set of financial & clinical data
- Value of Lab to total cost of care

Macro Healthcare Trends – Industry Disrupters

Consumerism and Data Analytics Shape the Future of Healthcare Delivery



Amazon – Chase –
Berkshire Hathaway Alliance

- Already obtained licenses for DME distribution in 48 states
- Could partner with PBMs
- Amazon and Alexa capabilities (schedule office visit; virtual house calls)
- AI based in-home healthcare & diagnostics



CVS – Aetna Merger
Cigna/ Express Scripts

- Both mergers designed to control rising medical costs and provide data analytics
- CVS has 9700 pharmacies & 1100 walk in clinics
 - Minute Clinic vs. ER option or Physician visit
- 3 largest PBMs become vertically integrated with insurers (UHC/Catamaran)



Walmart – Humana

- Combining retail pharmacies with a PBM
- Data analytics building a 360 view of consumer
- Medicare Advantage growth – better care at lower cost
- Delivering care close to consumer



Pharma Invests in Labs
(Novartis, Roche, Opko)

- Companion Dx drive therapeutic drug sales
- Big Data (NGS) identifies cancer related DNA
- Big Data helps physicians optimize test orders and treatment choices
- Big Data helps manage population health and control medical costs

Amazon's Strategy to Enter Healthcare

Consumerism and Data Analytics Shape the Future of Healthcare Delivery

Step 1: Provide the Best Consumer Experience \$50-\$100 BN

- Start with low hanging fruit like OTC, devices/supplies, and cash pay generics

Impact on Incumbents:

Amazon is another participant in a consolidated space creating pressure on certain business lines, but it is not game-changing

Step 2: Make it Easy to Manage Health \$100-\$500 BN

- Leverage Alexa to help consumers manage healthcare more broadly
 - Bring Amazon-era decision support to help customers find the best value care
 - Expand the scope of drug products through PBM/payor partnerships

Impact on Incumbents:

Drug retailers begin to lose strategic control and market share, but other stakeholders (pharma, payors) partner with Amazon

Step 3: Become the New Front Door to Health by Owning the Consumer \$500+ BN

- Integrate virtual care with Alexa
 - Facilitate healthcare information and transactions
 - Incorporate in-home health services through Uber network of professionals and care givers

Impact on Incumbents:

Game over when Amazon owns patient data and influences consumer choice of where to access care

Amazon, Apple, Google, Microsoft Plan to Enter EHR/EMR Market

- Amazon IT team (1492) focused on interoperability of EHRs
- Apple health working on personal health record integration into Apple IOS for iPhone, iPad
- Microsoft working on analytic tools & data storage
- Google working on data processing & storage

It's Not Just About the Data; It Is a Change of Mindset

Commonality of products that succeed: Quality of life solutions - Improve the Human Condition – Make lives better



- Outdated, unscalable data technologies
- Data Silos
- Incomplete “cloud strategy”
- Lack of data engineering/science talent
- Rationalizing data platform roadmap to evolving business models
- Driving organizational alignment

- Establish a vision for the role of data in your organization
- Leadership commitment and organizational alignment
- Adopt best-in-class technologies throughout the organization that align with your data needs
- Develop easy to convey use cases that demonstrate thought leadership
- Develop a plan of execution and align all resources behind the plan





Thank You!

