



RWE: Win-Win Opportunities for Pharmas and Payers

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The PRISME Forum



Why Real World Evidence?

The Burden of Chronic Disease: A Noticeable Gap in Care in Key Areas

An Intensifying
Problem

5% of the
population makes up
half of US
healthcare costs¹

A Growing Issue

By 2030, chronic
diseases will affect
half of all Americans²

A Costly Situation

75% of total
healthcare costs go
toward treating
chronic disease³

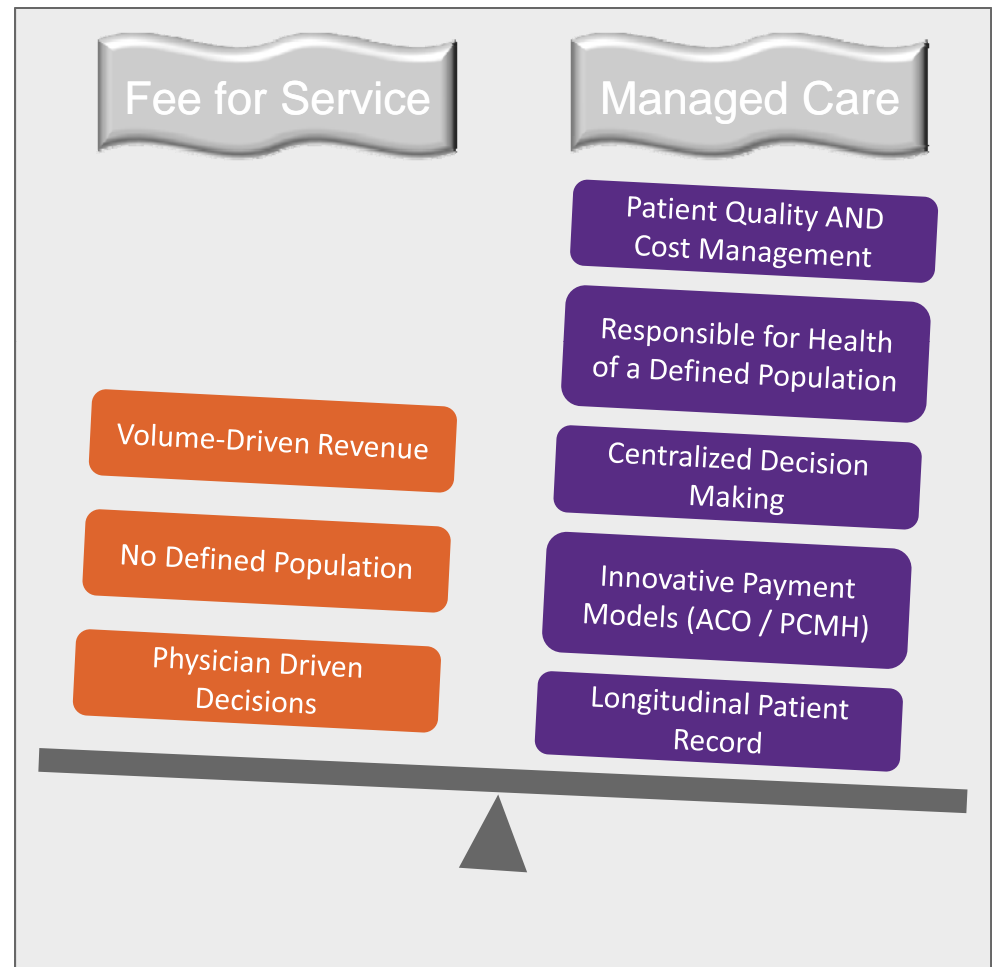
¹ <http://facts.kff.org/chart.aspx?ch=1344>

² http://www.fightchronicdisease.org/sites/default/files/docs/GrowingCrisisofChronicDiseaseintheUSfactsheet_81009.pdf

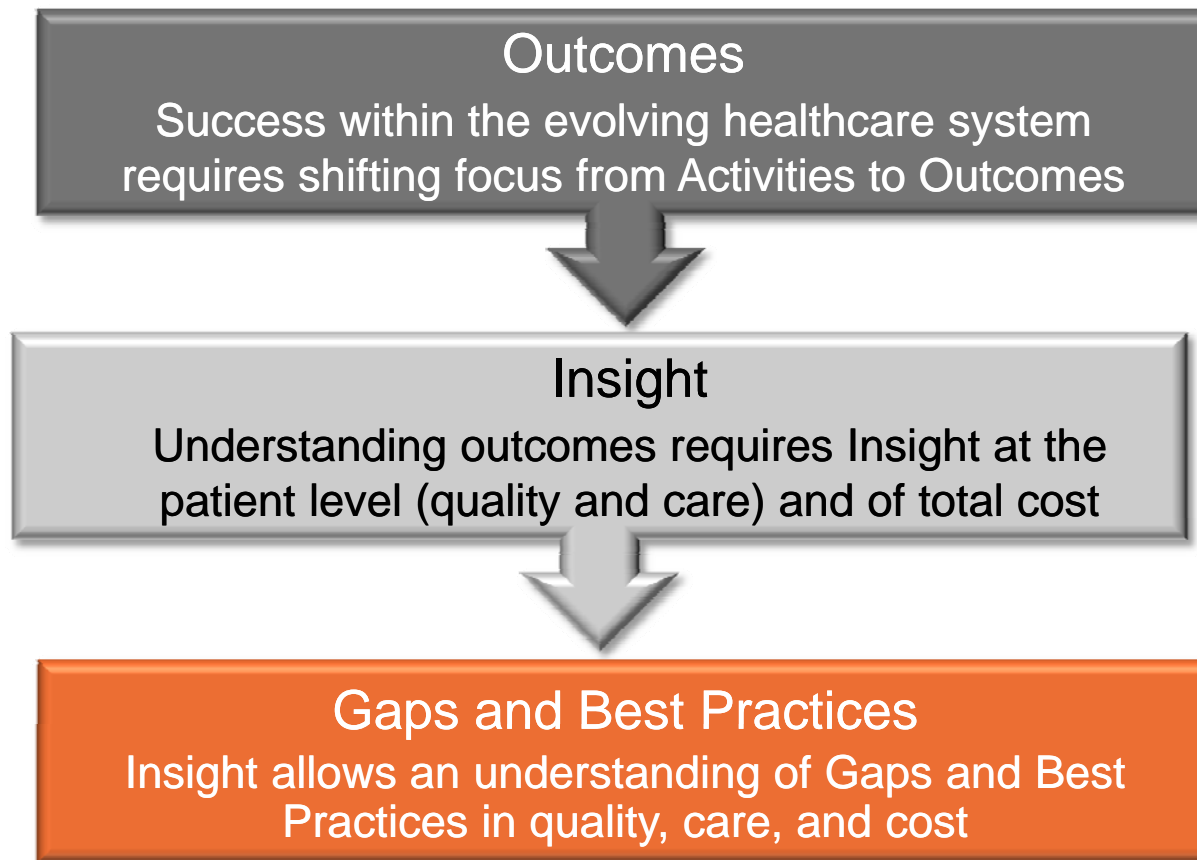
³ <http://www.kaiseredu.org/Issue-Modules/US-Health-Care-Costs/Background-Brief.aspx>

Innovative Payment Models are Increasing in Prevalence

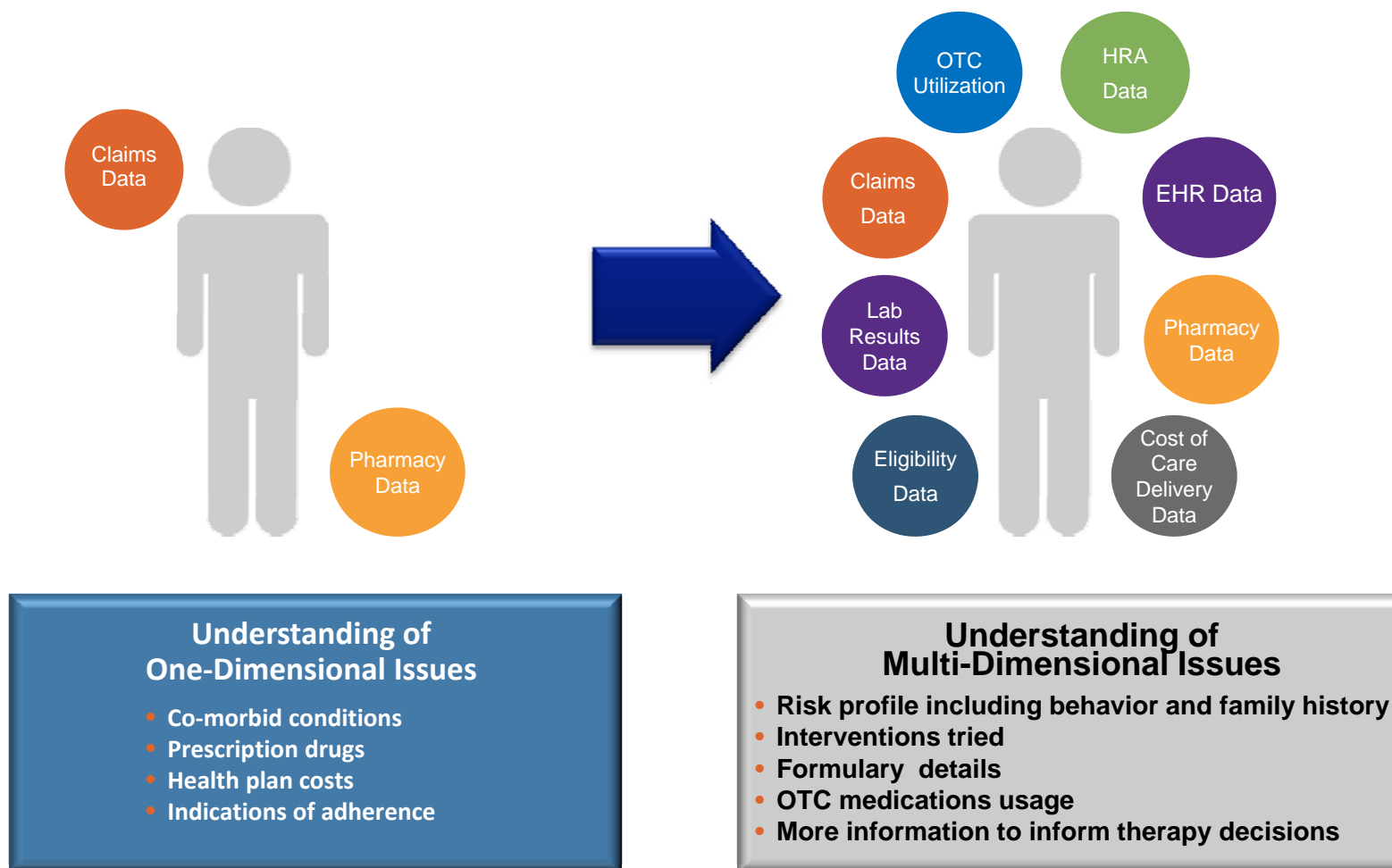
- Emerging US payment models are seeking to align provider and payer interests
- Models with a degree of shared risk continue to evolve, across the care continuum:
 - Pay-for-Performance
 - Hospital-Physician Bundling
 - Episodic Bundling
 - Shared-Savings Models (ACO, PCMH)
- In order to be successful, healthcare entities will need new systems and capabilities



Shifting from Process to Outcomes Measures



Improve Outcomes with a 360° View of the Patient



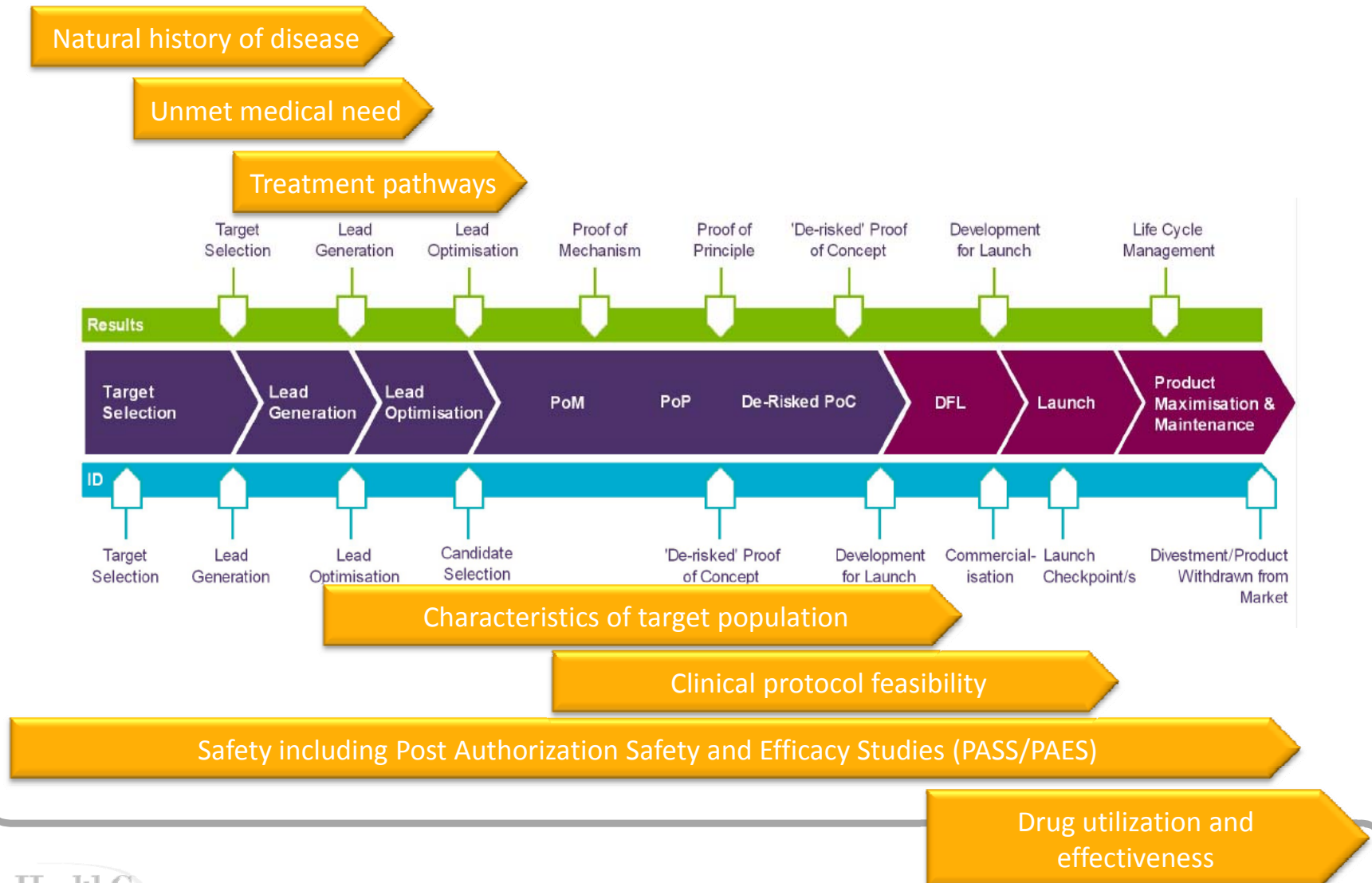
Real World Evidence: Potential Application

Through innovative and advanced analytical deliverables developed using claims and electronic health record data, RWE would help support:

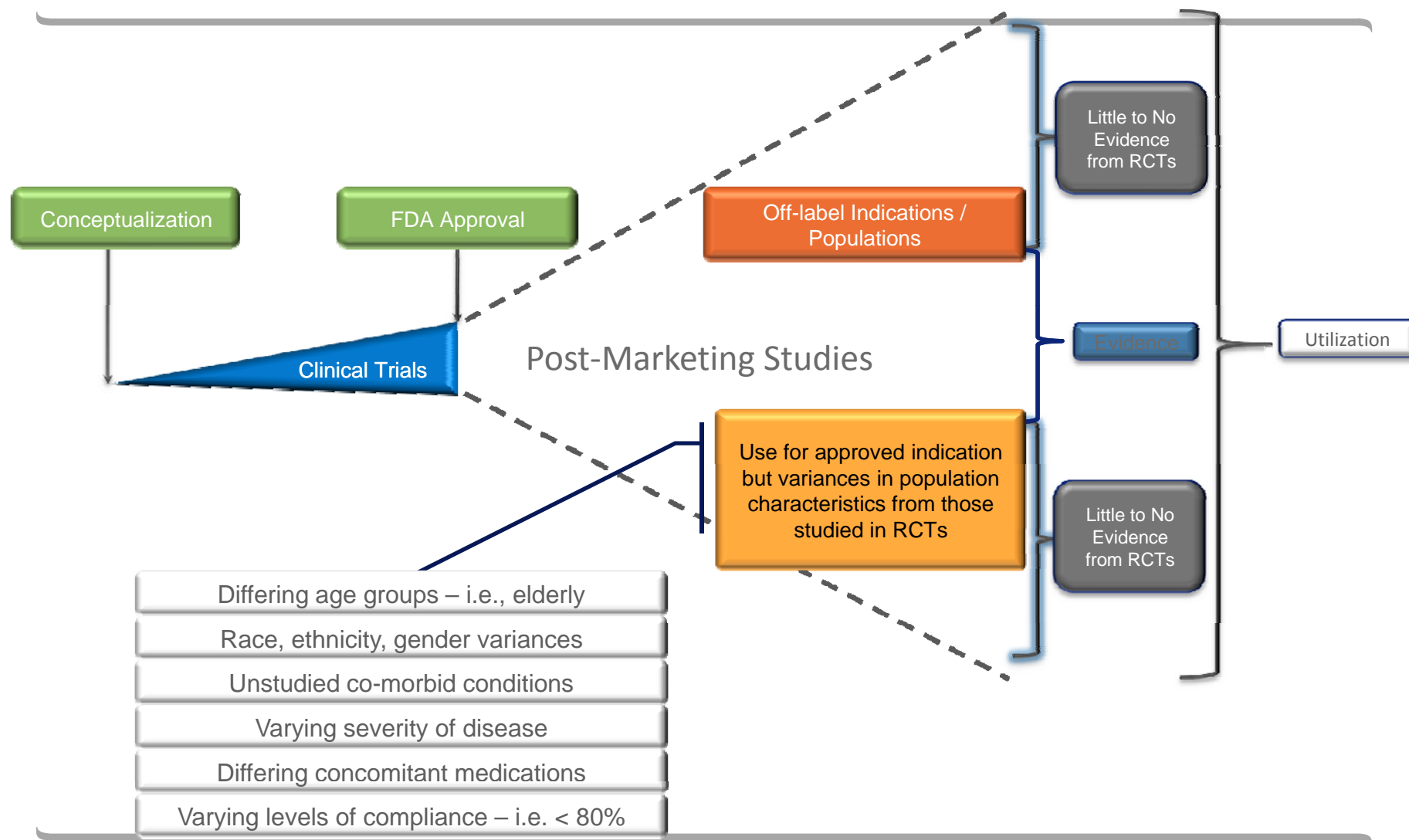
- **Patients:** Identifying unmet medical needs, improving quality, outcomes, and coordination of patient centered care
- **IDNs / Hospitals:** Improving quality of care and outcomes while providing insights into cost containment
- **Payers:** Analysis of new payment models, risk and outcomes-based contracts
- **Pharma / Biotech:** Market analysis to support product innovation for development of reimbursable products and to demonstrate the value of our medicines in improving health outcomes and total cost of care

RWE Support Across the Product Life Cycle

Examples of



Root of the Evidence Gap



Integration of Key Clinical Data

•Incorporation of chart-based elements including:

- Vitals
- Physical findings
- Immunizations
- Social Functioning
- Family history
- Prescribed medications (including OTC)
- Test results
- Other

Vital Signs

Person ID	Service Department	Observation Date	Observation	Observation Type	Observation Type	Observation Value	Observation Status	Reference Range
PER100001533	Vital Signs	2010-04-18	Diastolic BP	Diastolic BP	NUMERIC	72	Final	60-79
PER100001533	Vital Signs	2010-09-13	Diastolic BP	Diastolic BP	NUMERIC	60	Final	60-79
PER100001533	Vital Signs	2010-04-18	Pulse Description	Pulse Description	TEXT	regular	Final	-
PER100001533	Vital Signs	2009-12-20	Pulse Description	Pulse Description	TEXT	regular	Final	-
PER100001533	Vital Signs	2009-07-29	Pulse rate	Pulse rate	NUMERIC	87	Final	50-80
PER100001533	Vital Signs	2009-12-20	Pulse rate	Pulse rate	NUMERIC	74	Final	50-80
PER100001533	Vital Signs	2009-07-29	Respiratory Rate	Respiratory Rate	ONTOLOGY	no intercostal retractions or use of accessory mus	Final	-
PER100001533	Vital Signs	2010-04-18	Systolic BP	Systolic BP	NUMERIC	120	Final	<120 prehypertension
PER100001533	Vital Signs	2010-09-13	Systolic BP	Systolic BP	NUMERIC	105	Final	90-119
PER100001533	Vital Signs	2010-09-13	Weight	Weight	NUMERIC	188	Final	-
PER100001533	Vital Signs	2011-03-17	Weight	Weight	NUMERIC	192	Final	-

Physical Exam Results

Person ID	Service Department	Observation Date	Observation	Observation Type	Observation Type	Observation Value	Observation Status	Reference Range
PER100001533	EBM Physical Exam	2010-09-13	Abdomen Examination	Abdomen Examination	ONTOLOGY	no distension, soft and non-tender without guarding	Final	-
PER100001533	EBM Physical Exam	2009-12-20	Carotid Artery Examination	Carotid Artery Examination	ONTOLOGY	pulses full and symmetric; no bruits	Final	-
PER100001533	EBM Physical Exam	2009-12-20	Chest Percussion	Chest Percussion	ONTOLOGY	no dullness	Final	-
PER100001533	EBM Physical Exam	2009-12-20	Cranial Nerves Examination	Cranial Nerves Examination	ONTOLOGY	III-XII grossly intact	Final	-
PER100001533	EBM Physical Exam	2009-12-20	Diabetic Foot Exam	Diabetic Foot Exam	ONTOLOGY	yes	Final	-
PER100001533	EBM Physical Exam	2009-07-29	Eyes Examination	Eyes Examination	ONTOLOGY	conjunctiva and lids normal	Final	-
PER100001533	EBM Physical Exam	2009-12-20	Ear Examination	Ear Examination	ONTOLOGY	normal gait, no strabismus	Final	-
PER100001533	EBM Physical Exam	2009-12-20	Mood-Affect	Mood-Affect	ONTOLOGY	no appearance of anxiety, depression, or agitation	Final	-
PER100001533	EBM Physical Exam	2009-12-20	Peripheral Vasculture Examination	Peripheral Vasculture Examination	ONTOLOGY	no cyanosis, clubbing, or edema	Final	-
PER100001533	EBM Physical Exam	2009-07-29	Reflex - Deep Tendon Neurologic Exam	Reflex - Deep Tendon Neurologic Exam	ONTOLOGY	2 and symmetric with no pathological reflexes	Final	-
PER100001533	EBM Physical Exam	2010-09-13	Thyroid Examination	Thyroid Examination	ONTOLOGY	no nodules, masses, tenderness, or enlargement	Final	-

Immunizations

Person ID	Service Department	Observation Date	Observation	Observation Type	Observation Type	Observation Value	Observation Status	Reference Range
PER100001533	Immunization	2010-02-04	H1N1 Administered By	H1N1 Administered By	TEXT	MEDICAL PROVIDER	Final	-
PER100001533	Immunization	2010-02-04	H1N1 Administration Site	H1N1 Administration Site	ONTOLOGY	Left Deltoid-LD	Final	-
PER100001533	Immunization	2010-02-04	H1N1 Expiration Date	H1N1 Expiration Date	TEXT	06/07/2011	Final	-
PER100001533	Immunization	2010-02-04	H1N1 Lot Number	H1N1 Lot Number	TEXT	UP101AA	Final	-
PER100001533	Immunization	2010-02-04	H1N1 Manufacturer	H1N1 Manufacturer	ONTOLOGY	Sanofi Pasteur-PMC	Final	-
PER100001533	Immunization	2010-02-04	H1N1 Route of Administration	H1N1 Route of Administration	ONTOLOGY	Intramuscular-IM	Final	-
PER100001533	Immunization	2010-02-04	H1N1 Vaccine Information	H1N1 Vaccine Information	TEXT	10/02/09	Final	-

Social Functioning

Person ID	Service Department	Observation Date	Observation	Observation Type	Observation Type	Observation Value	Observation Status	Reference Range
PER100001533	EBM Social History	2009-12-20	Social History Reviewed	Social History Reviewed	ONTOLOGY	no changes required	Final	-
PER100001533	EBM Social History	2010-04-18	Social History Reviewed	Social History Reviewed	ONTOLOGY	no changes required	Final	-
PER100001533	EBM Social History	2009-12-20	Social History Status	Social History Status	ONTOLOGY	no changes required	Final	-
PER100001533	EBM Social History	2010-09-13	Social History Status	Social History Status	ONTOLOGY	no changes required	Final	-

Key to Insight Generation

Persisting Longitudinal Patient Record (LPR) at the Database Level

Incorporation of vital signs

	A	D	E	F	H	J	L	M	N	O	P	Q
4	Result Indexes											
5		service_department	observation_date	observation_time	observation_type	observation_value	reference_range	normality	unit			
302	PER100001533	Vital Signs	3/18/2011	0:00:08	Diastolic BP	70	60-79		mmHg			
303	PER100001533	Vital Signs	3/17/2011	20:00:00	Diastolic BP	70	60-79					
304	PER100001533	Vital Signs	9/13/2010	20:00:00	Diastolic BP	60	60-79					
305	PER100001533	Vital Signs	4/18/2010	20:00:00	Diastolic BP	72	60-79					
306	PER100001533	Vital Signs	12/20/2009	19:00:00	Diastolic BP	76	60-79					
307	PER100001533	Vital Signs	7/29/2009	20:00:00	Diastolic BP	70	60-79					
308	PER100001533	Vital Signs	3/18/2011	0:00:08	Measured Weight	192	-		lb			
309	PER100001533	Vital Signs	3/18/2011	0:00:08	Pulse rate	64	50 - 80		/min			
310	PER100001533	Vital Signs	3/17/2011	20:00:00	Pulse rate	64	50 - 80					
311	PER100001533	Vital Signs	9/13/2010	20:00:00	Pulse rate	68	50 - 80					
312	PER100001533	Vital Signs	4/18/2010	20:00:00	Pulse rate	78	50 - 80					
313	PER100001533	Vital Signs	12/20/2009	19:00:00	Pulse rate	74	50 - 80					
314	PER100001533	Vital Signs	7/29/2009	20:00:00	Pulse rate	87	50 - 80					
315	PER100001533	Vital Signs	3/18/2011	0:00:08	Systolic BP	105	90-119		mmHg			
316	PER100001533	Vital Signs	3/17/2011	20:00:00	Systolic BP	105	90-119					
317	PER100001533	Vital Signs	9/13/2010	20:00:00	Systolic BP	105	90-119					
318	PER100001533	Vital Signs	4/18/2010	20:00:00	Systolic BP	120	<120 prehypertension 130-139					
319	PER100001533	Vital Signs	12/20/2009	19:00:00	Systolic BP	110	90-119					
320	PER100001533	Vital Signs	7/29/2009	20:00:00	Systolic BP	120	<120 prehypertension 130-139					
321	PER100001533	Vital Signs	3/17/2011	20:00:00	Weight	192	-					
322	PER100001533	Vital Signs	9/13/2010	20:00:00	Weight	189	-					
323	PER100001533	Vital Signs	4/18/2010	20:00:00	Weight	190	-					
324	PER100001533	Vital Signs	12/20/2009	19:00:00	Weight	190	-					
325	PER100001533	Vital Signs	7/29/2009	20:00:00	Weight	183	-					
326	PER100001533	Vital Signs	3/17/2011	20:00:00	Weight (kg)	87.27	-					
327	PER100001533	Vital Signs	9/13/2010	20:00:00	Weight (kg)	85.91	-					
328	PER100001533	Vital Signs	4/18/2010	20:00:00	Weight (kg)	86.36	-					
329	PER100001533	Vital Signs	12/20/2009	19:00:00	Weight (kg)	86.36	-					
330	PER100001533	Vital Signs	7/29/2009	20:00:00	Weight (kg)	83.18	-					

Key to Insight Generation

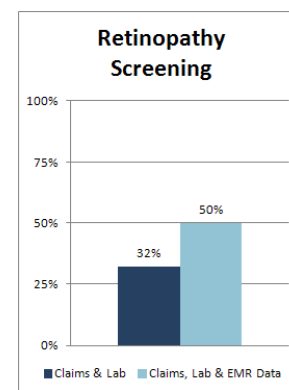
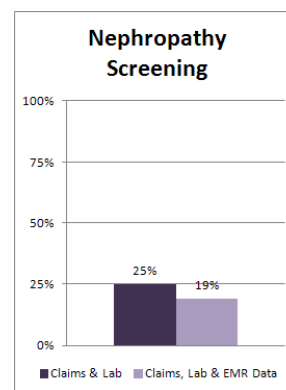
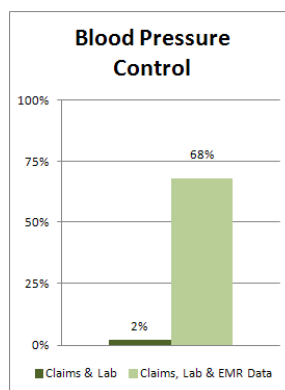
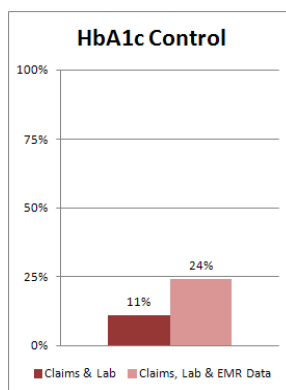
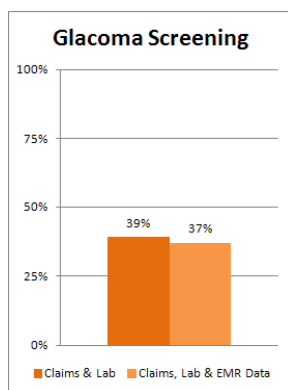
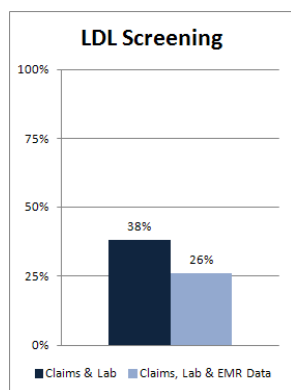
Persisting Longitudinal Patient Record (LPR) at the Database Level

	A	D	E	F	H	J	L	M	N	O	P	Q
4	Result Indexes											
5		service_department	observation_date	observation_time	observation_type	observation_value	reference_range	normality	unit			
6	PER100001533	Blood Count Test	4/18/2010	20:00:00	Hemoglobin A1c		5.8	-				
7	PER100001533	Blood Count Test	3/17/2011	20:00:00	Hemoglobin A1c		7.2	-				
69	PER100001533	Evaluation and Management	9/13/2010	20:00:00	Orientation	oriented to time, place, and person	-					
70	PER100001533	Evaluation and Management	12/20/2009	19:00:00	Gait Examination	normal gait; no ataxia	-					
87	PER100001533	Evaluation and Management	9/13/2010	20:00:00	Coronary Heart Disease (CHD). Calculated 10 yr Mortality Risk		18	-				
88	PER100001533	Evaluation and Management	9/13/2010	20:00:00	Past Medical History	reviewed - no changes required	-					
93	PER100001533	Evaluation and Management	9/13/2010	20:00:00	Mood-Affect	no appearance of anxiety, depression, or agitation	-					
94	PER100001533	Evaluation and Management	4/18/2010	20:00:00	Mood-Affect	no appearance of anxiety, depression, or agitation	-					
95	PER100001533	Evaluation and Management	3/17/2011	20:00:00	Social History Reviewed	reviewed - no changes required	-					
98	PER100001533	Evaluation and Management	12/20/2009	19:00:00	History of Peripheral Vascular Disease	no	-					
99	PER100001533	Evaluation and Management	12/20/2009	19:00:00	History of Hypertension	no	-					
100	PER100001533	Evaluation and Management	12/20/2009	19:00:00	History of Diabetes Mellitus	yes	-					
101	PER100001533	Evaluation and Management	12/20/2009	19:00:00	History of CVA or TIA	no	-					
102	PER100001533	Evaluation and Management	12/20/2009	19:00:00	History of Coronary Artery Disease	no	-					
104	PER100001533	Evaluation and Management	9/13/2010	20:00:00	Chief Complaint	Lipid Management	-					
108	PER100001533	Evaluation and Management	12/20/2009	19:00:00	History of HDL (high density lipoproteins) <35	yes	-					
119	PER100001533	Laboratory	3/17/2011	20:00:00	Total Protein		7.1	-				
120	PER100001533	Laboratory	9/13/2010	20:00:00	T Chol/HDL Ratio		3.95	-				
121	PER100001533	Laboratory	9/13/2010	20:00:00	Glucose-Serum		119	-				
228	PER100001533	Medical Care	2/4/2010	19:00:00	H1N1 Expiration Date		6/7/2011	-				
229	PER100001533	Medical Care	7/29/2009	20:00:00	Respiratory Rate	no intercostal retractions or use of accessory mus	-					
241	PER100001533	Patient Exam/Assessment	12/20/2009	19:00:00	Diabetic Foot Exam	yes	-					
282	PER100001533	Pharmacy	2/1/2012	19:00:00	Brand Description	ONETOUCH ULTRA TEST STRP	-					
283	PER100001533	Pharmacy	2/1/2012	19:00:00	Brand Description	VITAMIN D 1000 UNIT CAPS	-					
284	PER100001533	Pharmacy	2/4/2010	19:00:00	H1N1 Lot Number	UP101AA	-					
285	PER100001533	Pharmacy	2/4/2010	19:00:00	H1N1 Route of Administration	Intramuscular-IM	-					
286	PER100001533	Pharmacy	2/4/2010	19:00:00	H1N1 Manufacturer	Sanofi Pasteur-PMC	-					
287	PER100001533	Pharmacy	4/18/2010	20:00:00	No Known Medications	F	-					
288	PER100001533	Preventive Medicine	2/4/2010	19:00:00	H1N1 Administered By	Pearce, LPN, Sandra	-					
289	PER100001533	Preventive Medicine	2/4/2010	19:00:00	H1N1 Vaccine Information		10/2/2009	-				
290	PER100001533	Preventive Medicine	9/13/2010	20:00:00	H1B 4 Months		51	-				
291	PER100001533	Preventive Medicine	4/18/2010	20:00:00	H1B 4 Months		79	-				
296	PER100001533	Preventive Medicine	7/23/2009	20:00:00	H1B 4 Months		17	-				
297	PER100001533	Preventive Medicine	2/4/2010	19:00:00	H1N1 Administration Site	Left Deltoid-LD	-					
298	PER100001533	Tumor Marker	1/15/2010	19:00:00	Prostate-specific Ag. Serum		6	<=4.0	Abnormal-High	ng/mL		
299	PER100001533	Tumor Marker	1/15/2010	19:00:00	% Free PSA		22	>25	Abnormal-Low	%		
300	PER100001533	Tumor Marker	1/15/2010	19:00:00	Risk of Prostate Cancer	16 > THE ESTIMATED PROBABILITY OF CANCER VARIES WITH AGE. ETHNICITY, FAMILY HISTORY, AND DIGITAL RECTAL EXAMINATION (DRE) RESULTS. REFERENCE: CATALONA, ET AL.: JAMA 279: 1532-1547 (1998)	-		%			
301	PER100001533	Tumor Marker	1/15/2010	19:00:00	PSA, Free		1.3	-		ng/mL		

Clinical Enrichment

Valid Quality of Care Measurement

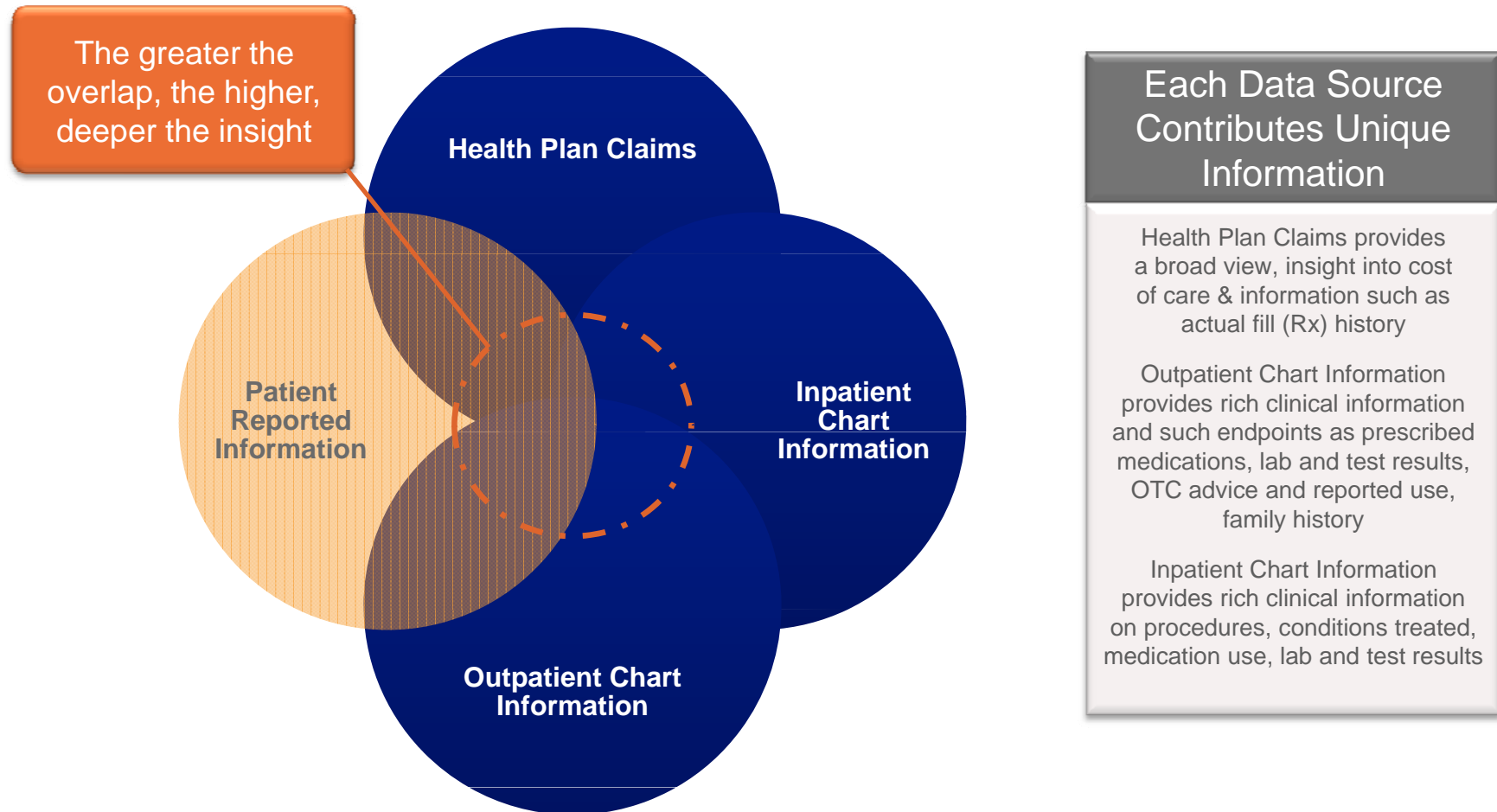
Numerator Name*	Claims & Lab			Claims, Lab & EMR Data			% Yield		
	Numerator	Denominator	Percentage	Numerator	Denominator	Percentage	Numerator	Denominator	Percentage
HEDIS LDL Cholesterol Screening - Compliant	30	79	38%	26	101	26%	-13%	28%	-32%
HEDIS Glaucoma Screening - Compliant	12	31	39%	28	75	37%	133%	142%	-4%
HEDIS HbA1c Control - Good	5	46	11%	20	82	24%	300%	78%	124%
HEDIS Blood Pressure <140/90 & Within Year - Compliant	1	63	2%	96	141	68%	9500%	124%	4189%
HEDIS Nephropathy Screening - Compliant	12	48	25%	15	80	19%	25%	67%	-25%
HEDIS Retinopathy Screening - Compliant	12	37	32%	25	50	50%	108%	35%	54%
Diabetes Total:	72	304	24%	210	529	40%	192%	74%	68%



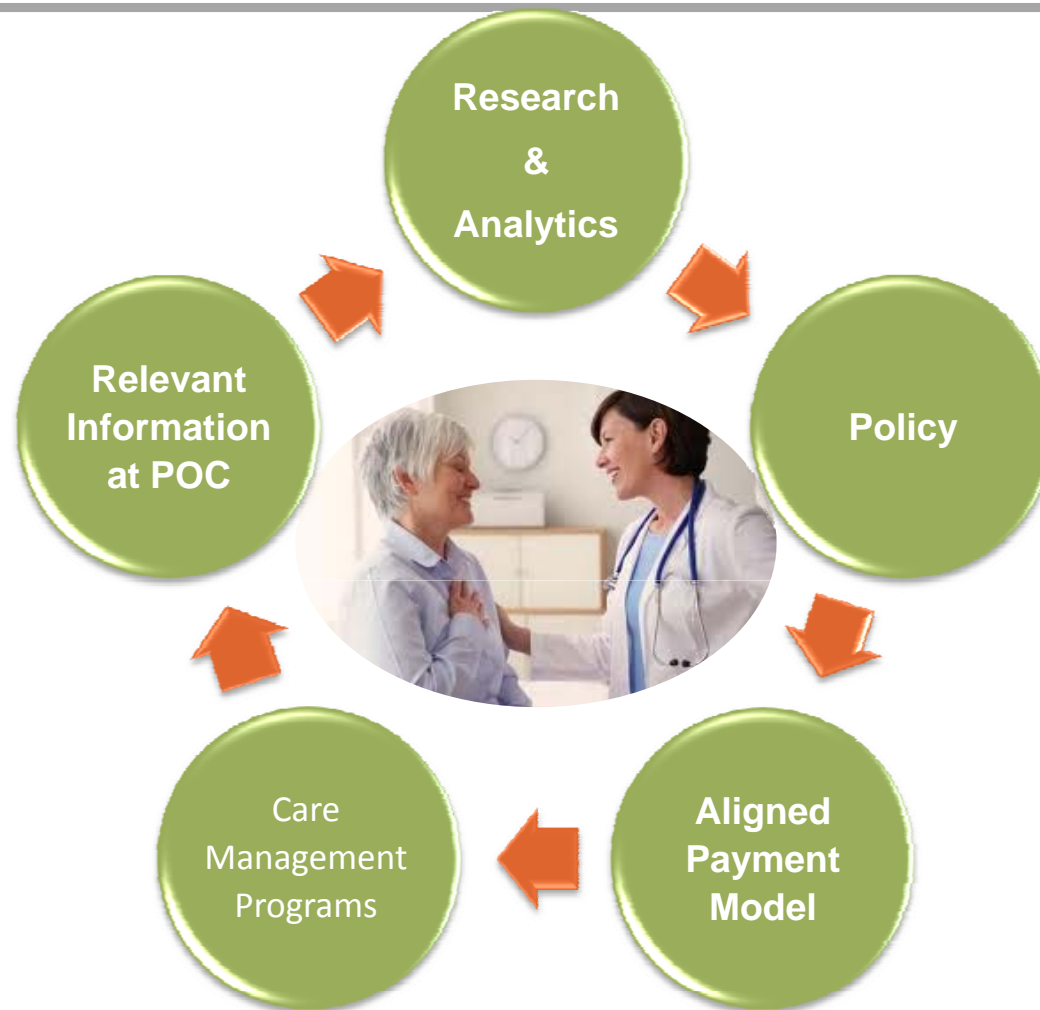
*Note: ~1500 member population. Select enrichment measures only

Electronic Healthcare Data Proliferation

Value is Unlocked with Integration



A Necessary Connection



Key Learnings to Date



Stakeholder alignment is key



Many are not yet ready from a technological perspective



Trust between parties has to be established



Understanding of data complexity and ability to integrate data is essential



Development and implementation costs can be high



The results can be transformational for health and healthcare

Risks of Big Data in RWE

- Addressing issues of semantic interoperability and disparate ontologies and nomenclatures
- Statistical significance needs to correlate with clinical and economic significance
- HIPAA compliance becomes more complicated; especially in rare diseases
- State specific regulatory framework
- Awareness of data limitations and inapparent confounders
- Most reporting software has not been designed to integrate detailed clinical information

RWE Support Across the Product Life Cycle

Examples of

