Real World Data and Evidence
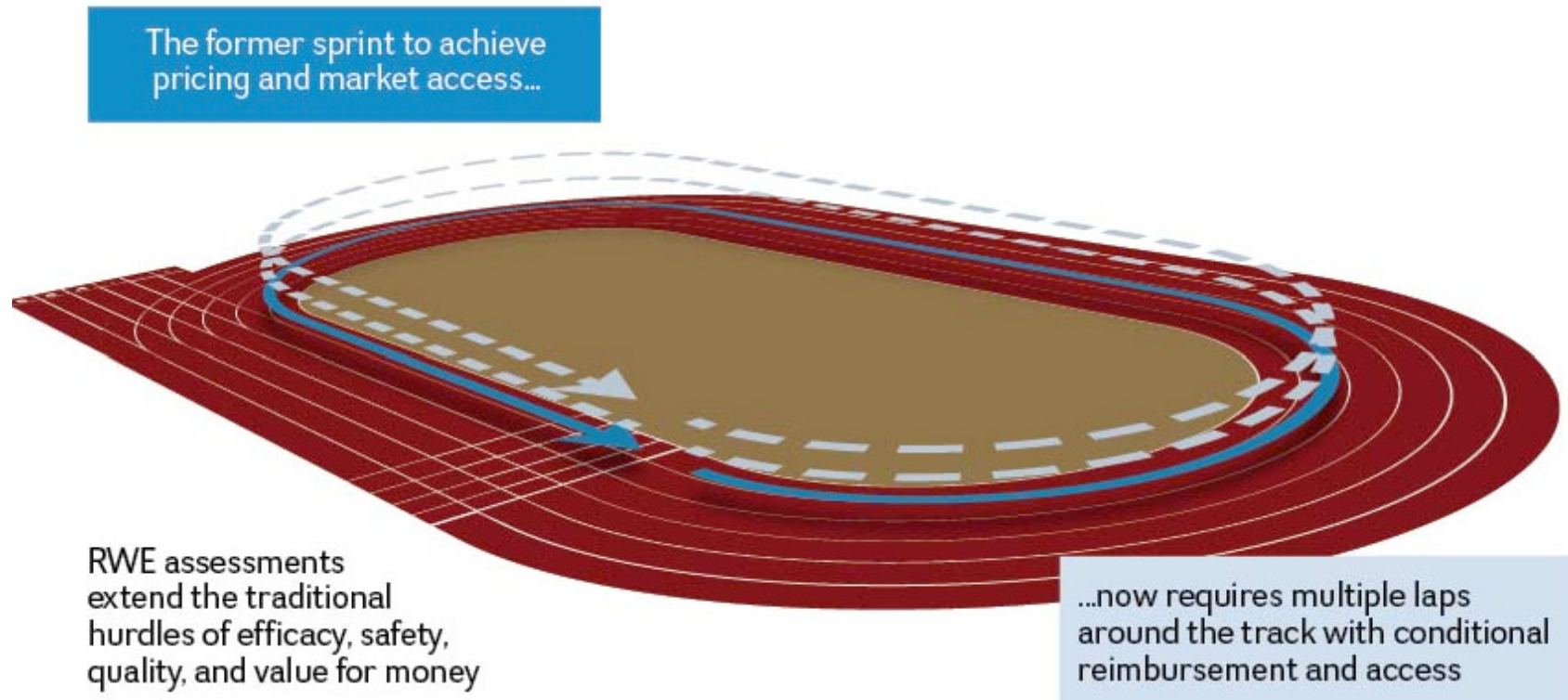# A Framework and Process for Engagement

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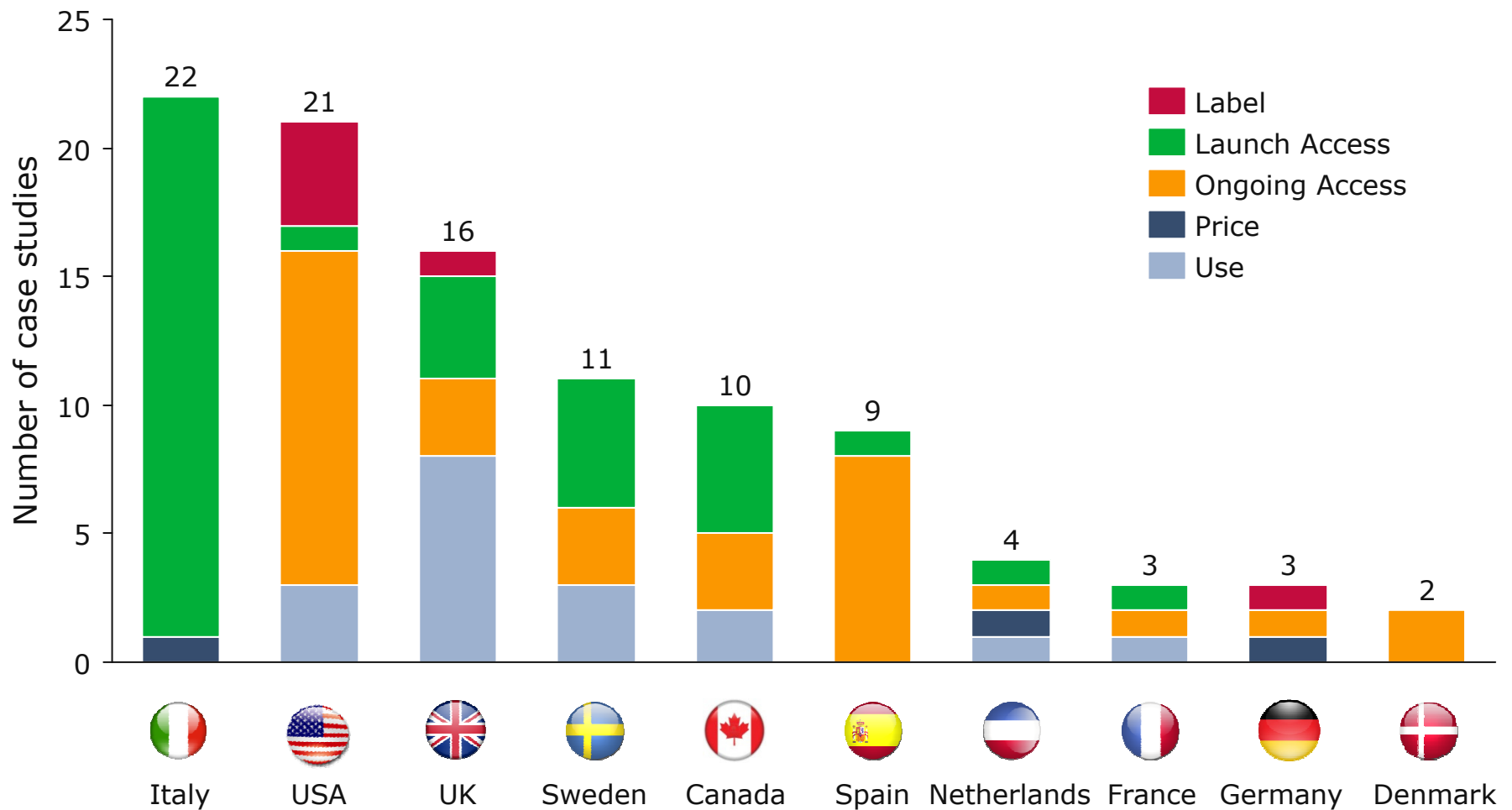
PRISME Forum
October 16, 2013

RWE is now required across the lifecycle of a product

The former sprint to achieve pricing and market access...

RWE assessments extend the traditional hurdles of efficacy, safety, quality, and value for money

...now requires multiple laps around the track with conditional reimbursement and access

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RWE impact is increasing across markets

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Required Shift in Operating Model

	Status Quo	Unlocking the Full Potential of Information
Timing of Evidence Delivery	At launch	Post-launch
Type of Data	RCT	Real-world
Outcomes Research	Prospective and inflexible	Retrospective, predictive, and flexible
Impetus for New Evidence Generation	Product or market shock	Planned and proactive
Approach	Siloed and transactional	Collaborative and constructive

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Clients are taking transformation beyond RWE

〉〉 **Focus** the organization on highest priorities
by tying insights to business economics

〉〉 **Allocate** resources more effectively
by understanding what creates and destroys value

〉〉 **Create a culture of one version of truth**
by providing a common language and fact base for the organization

〉〉 **Develop** a better value proposition
by understanding customer needs and how to meet them

〉〉 **Innovate** faster and more successfully
by identifying unmet or latent needs and barriers to adoption

〉〉 **Adapt** more quickly to market changes
by anticipating customer responses to new entrants or competitor moves

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Pharmacos are levering 5 types of innovation

I Organizational Readiness	II Strategic Partnerships / investments	III Leveraged Data investments	IV Analytical Engine Rooms	V Customer Engagement
Crossing functional boundaries to establish RWE as a platform for innovation	Creating alliances and collaborations across industry accelerate data access and collaboration	Customized data Builds incorporating innovative approaches to linking new sources of data	Challenging conventional ways of supporting internal stakeholders	Using analytics to reach external stakeholders and risk-based engagement
Customer Facing Insight Engines	RWE Partnerships	TA-Specific Data Marts & Strategy	Cross Functional Analytic Model	Quality measures, Pay for performance

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...but fully seizing RWD opportunity takes time

Action taken

Column headers (maturity): No pharma | 1-3 leaders | 4-7 leaders | Most pharma

I — Organizational Readiness
- RWE as formal requirement in brand plan — *Most pharma*
- Clear leadership / accountability for RWE — *4-7 leaders*
- RWE Capability building (e.g., cross-functional training) — *1-3 leaders*
- Roll-out across all TAs/Brand /Geographies — *1-3 leaders*
- 3-5 yr horizon RWE planning & impact measurement — *No pharma*

II — Strategic Partnerships / investments
- Major data access initiatives /partnerships:
  - US — *4-7 leaders*
  - EU / Other regions — *1-3 leaders*

III — Leveraged Data investments
- Universal data & analysis platforms across all internal (RCT, PV) and easily accessible external data (e.g., US / UK) — *1-3 leaders*
- Targeted platform builds (e.g., oncology) for less accessible & global datasets — *4-7 leaders*

IV — Analytical Engine Rooms
- Creation of RWE COEs:
  - For HEOR/PMA/R&D (mainly in US) — *4-7 leaders*
  - Extension to commercial applications (or x-US) — *1-3 leaders*

V — Customer Engagement
- Provider tools for local population management / service design — *1-3 leaders*
- RWE based interventions in patient pathway (e.g., adherence) — *1-3 leaders*
- RWE-enabled P4P contracts — *1-3 leaders*

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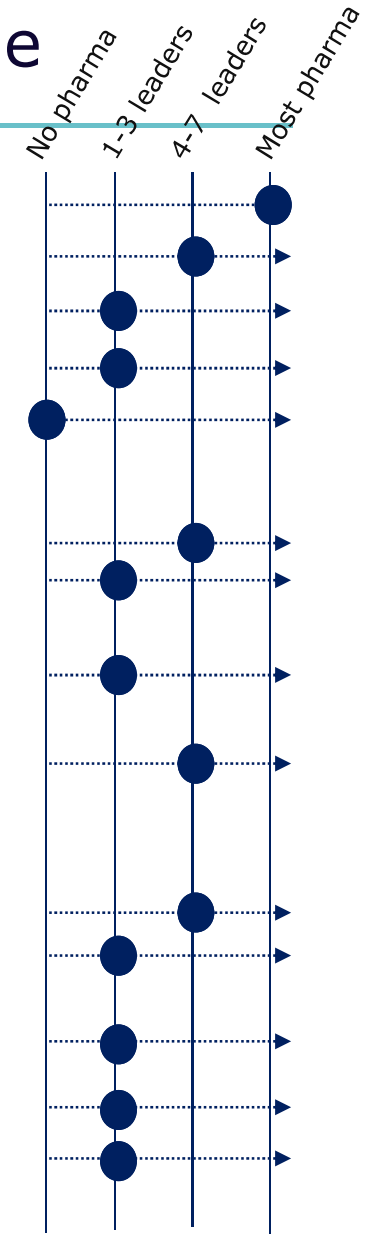
"Big Data" is near the pinnacle of Hype

Expectations Relative to Productivity Gain for New Technologies Over Time

Source: GigaOm

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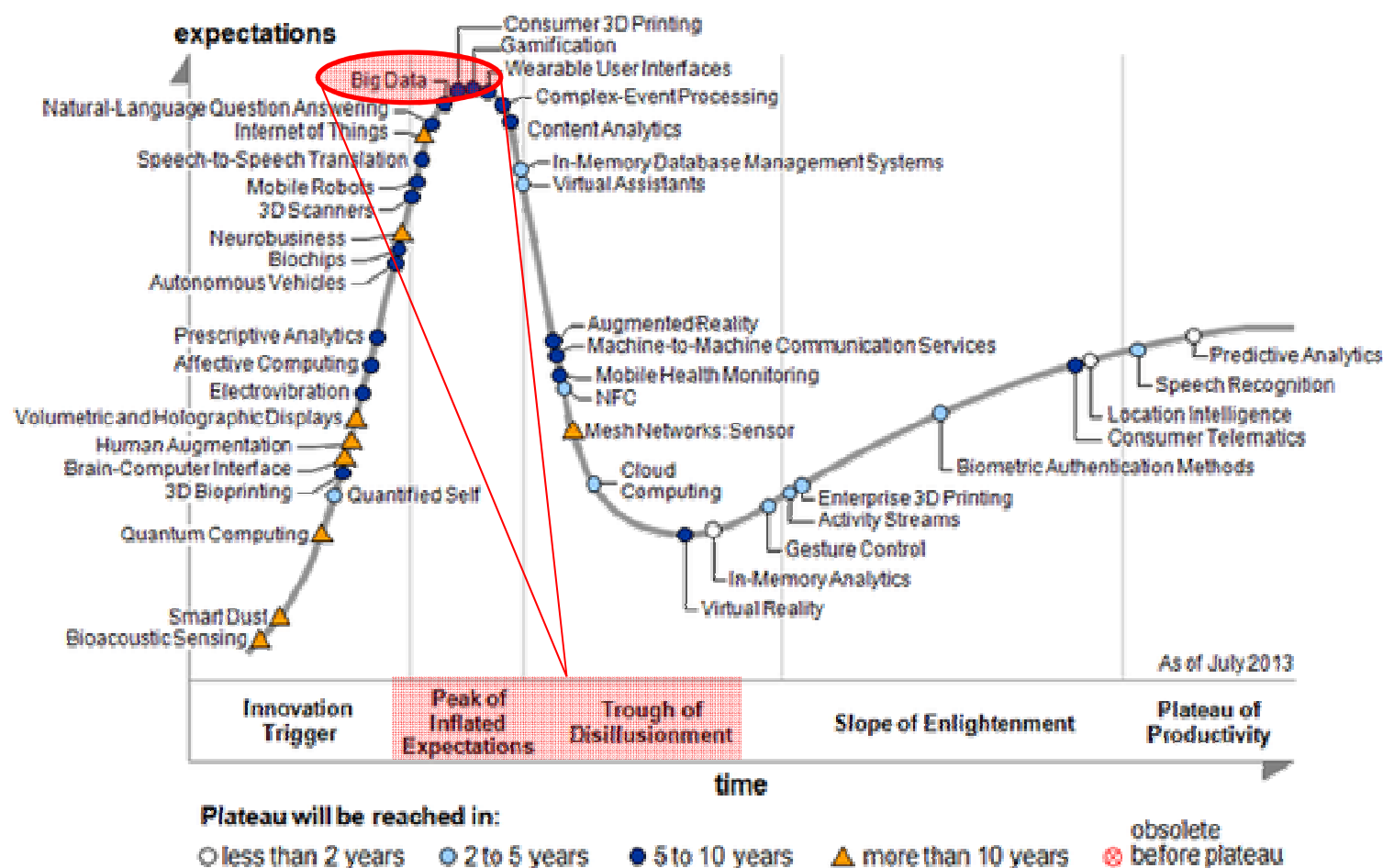
Proposed model for RWE engagement

Derive insights to inform decisions

What conclusions can I draw?

What does this mean for commercialization and for my customers?

Identify information needed and mechanisms for gathering

What information is needed?

Where can I obtain that information?

Define your RWE strategy

What are my objectives for RWE?

What issues or questions am I trying to address?

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Example goals for client RWE transformation

		Starting point	3 yr goal

Descriptive Epidemiology
- Local pop incidence, prevalence
- Sub-population characterisation
- Lab Tests XXX, YYY, ZZZ
- AAA risk evaluation in DDD patients

Patterns of Care
- Adherence to guidelines
- Treatment Patterns across sub-pops
- Patient journey on XXX/YYY

Outcomes of Care
- Rx impact on AAA outcomes
- LLL and MMM outcomes
- Disease Progression
- PPP/QQQ Safety & Tolerability
- Morbidity and mortality
- PROs

Relative Effectiveness
- XXX mono/combo vs. SoC
- YYY vs. SU
- XXX/YYY benefit/risk ratio

Starting point different in each pharmaco

■ Limited Ability   ■ Partial ability   ■ Full ability

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RWD – additional opportunities

Research

- Translational research (e.g. EMR linked to Biobanks)
- Portfolio optimization (asset evaluation etc.)
- Unmet need / disease understanding

Development

- Protocol feasibility and site optimisation
- Patient identification and recruitment
- Pragmatic & adaptive trials

Access and Launch

- HTA / HE / Budget Impact (PMA)
- Regulatory requirements
- Reimbursement / P4P contracts / risk share
- Launch planning / optimisation

Growth & Maintenance

- External communication (e.g., value demonstration/PMA)
- Innovative insight & commercial analytics (forecasting, performance management, etc.)
- Value added services (diagnosis, adherence etc.)

Enterprise platforms

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Example client platforms for RWD (& RWE)

Client	Therapeutic Area	Geography
Top-10 Bio pharma (EU)	Oncology	EU
Top-20 Bio-pharma (US)	Oncology	US
Top-10 Bio pharma (EU)	Opthalmology	EU, US, Australia, Japan
Top-10 Bio pharma (EU)	Multiple Sclerosis	EU, US
Top-20 Bio-pharma (US)	ADHD	US
Top-20 Bio-pharma (US)	Oncology	US
Top-10 Med device (US)	Urology	US

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Enterprise data platforms: case study

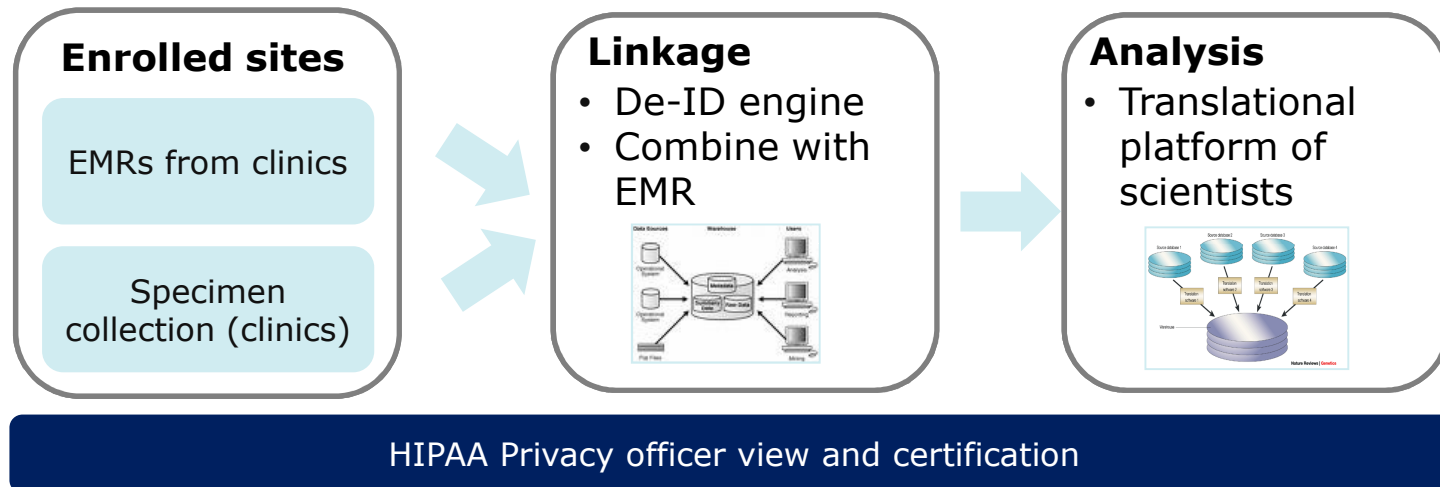| 2007	2008	2009	2010	2011
• Project initiation	• Aggregate EMR data feeds • Privacy & advisory boards • Design & delivery of standard reports • Analysis & publications to support FDA & CMS negotiations • Evaluation of data gaps • Plans for filling gaps	• Gap projects initiated • Evaluation of new data • Licensing of new data • Design & delivery of more reports • Launch of multiple research projects	• Gap projects Completed • Licensing of 6 new linkable data feeds • Projection of platform to US treated population • Platform linked to death records & claims data provider tumor registry	• Transition of platform to client • Evaluation and Analysis of patient subpopulation data • Launch of platform based research projects • 88 reports designed & delivered to clients
3 Abstracts (or posters)	**5 Abstracts 3 Manuscripts**	**1 Abstracts 3 Manuscripts**	**3 Abstracts 8 Manuscripts**	**4 Abstracts 3 Manuscripts**

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Innovative pharma looking for commercial insights...

Rx / LRx

- Overall product uptake vs. expected in segments
- Switch and cannibalization
- Uptake prediction models (e.g., NTB)

EMR / Claims

- Accurately profile the clinical state of patient at prescribing decision
- Profile prescribing in risk segments or on/off-label use

Social Media

- Measure awareness and attitudes to product across physicians and patients

Automated market research

- On-the-fly physician market research via EMR (pop-ups / CRM systems)

Innovative sources

- Mine clinical notes through NLP for physicians treatment rationale
- Closed physician forums
- Patient communities (patients like me)

Market research

- Physician sentiment / recall
- Patient sentiment / recall
- Formulary status
- Payer perception

Consumer / HCP profiles

- Deeper segmentation of patients and HCPs

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R&D: EMR & bio-specimen linkage

- Prospective tissue collection linked to EMR
- 21 sites and expanding
- 10k newly diagnosed patients/yr

Enrolled sites

EMRs from clinics

Specimen collection (clinics)

Linkage

- De-ID engine
- Combine with EMR

Analysis

- Translational platform of scientists

HIPAA Privacy officer view and certification

- Identify novel biomarkers
- Companion diagnostics/targeted therapeutics
- Optimize clinical trials

- Explore mechanisms of therapeutic response and toxicity
- Study disease development
- Expand existing drugs into new indications

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Next wave of impact: Value added services

Potential for use varies by market

Increasingly proactive →

External Actor

	Value demonstration (PMA) / Outcomes based marketing	Value added services (x-commercial)
Payer	Disease communication	Joint CER capabilities/programs
	Clinical claims validation	Payment construct, e.g. P4P
	Economic communications	Metric tracking; e.g. process care
	RCT claims	Adherence services
Provider	Disease communication	Benchmarking & metrics
	Economic communications	Burden/unmet need simulation
	Clinical claim validation	Adherence services
	RCT claims	Diagnosis services
Physician	Disease communication	Physician education
	Economic communications	Treatment pattern analysis
	Clinical claim validation	Analytic Services - Benchmarking
	RCT claims	

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