

The Evidence Evolution

A Pharma Perspective

Prisme SIG, 22.05.12

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Director, Payer and RWE Informatics | AstraZeneca



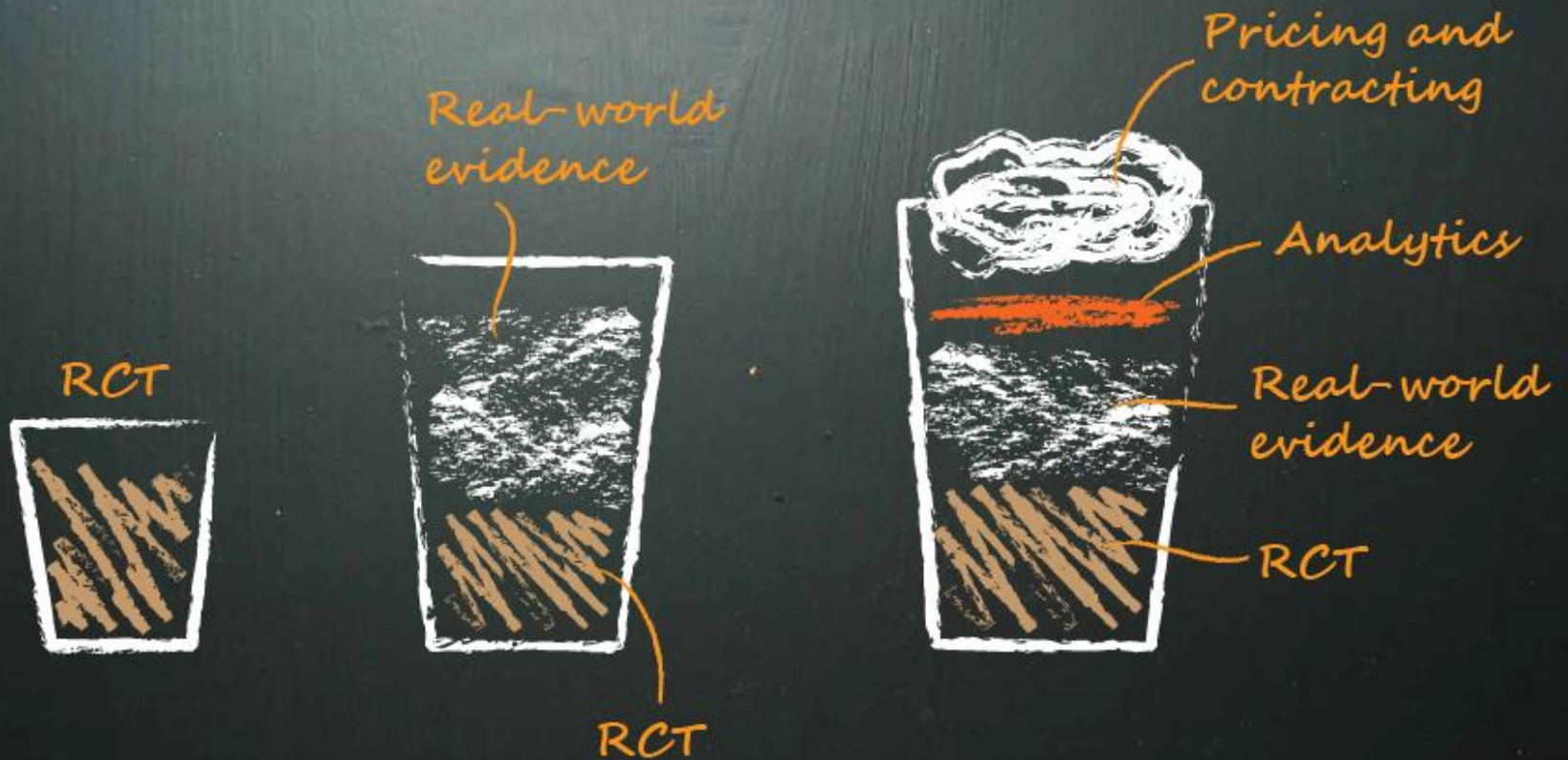
In the Beginning.....

One data customer, with predictable habits



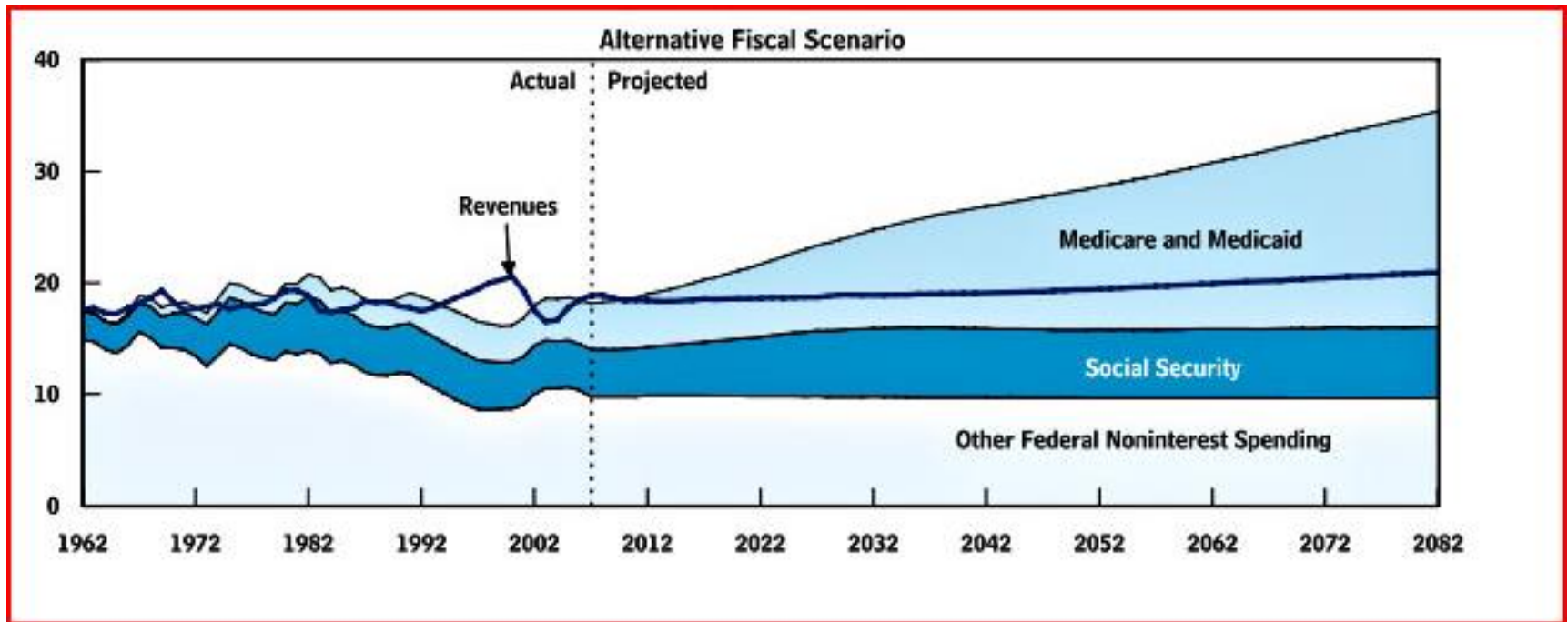
And now.....

Multiple data customers, many different tastes....



Fuelling the evolution I

“Our frightening fiscal future”*



*Congressional Budget Office, Long Term Budget Outlook, June 2011

And.....



Fuelling the evolution II

“The information explosion”

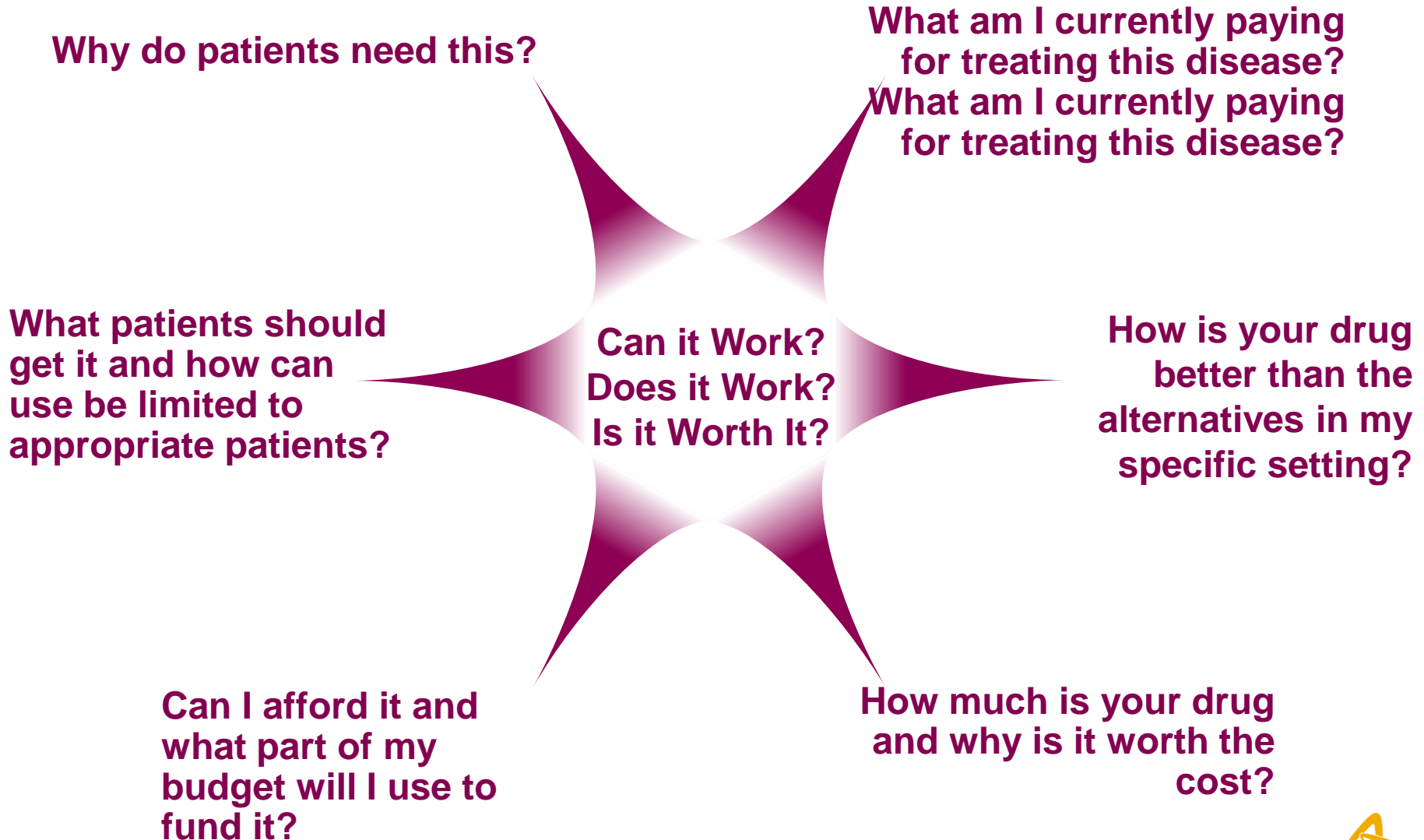


“The adoption of EHRs in the ambulatory setting has doubled in about two years and the Federal government’s incentive program for Meaningful Use is likely the primary driver. “

Gilad J. Kuperman, AMIA Board Chair



We need to be able to answer the Payer “Moment of Truth” Questions



Real World Evidence

Application to Pharma



Improving clinical development through understanding treatment and outcome diversity

Minimizing decision uncertainty through demonstrating relevance at product introduction and on market claim validation

Creating a “learning healthcare system” through performance indicators, information and incentives



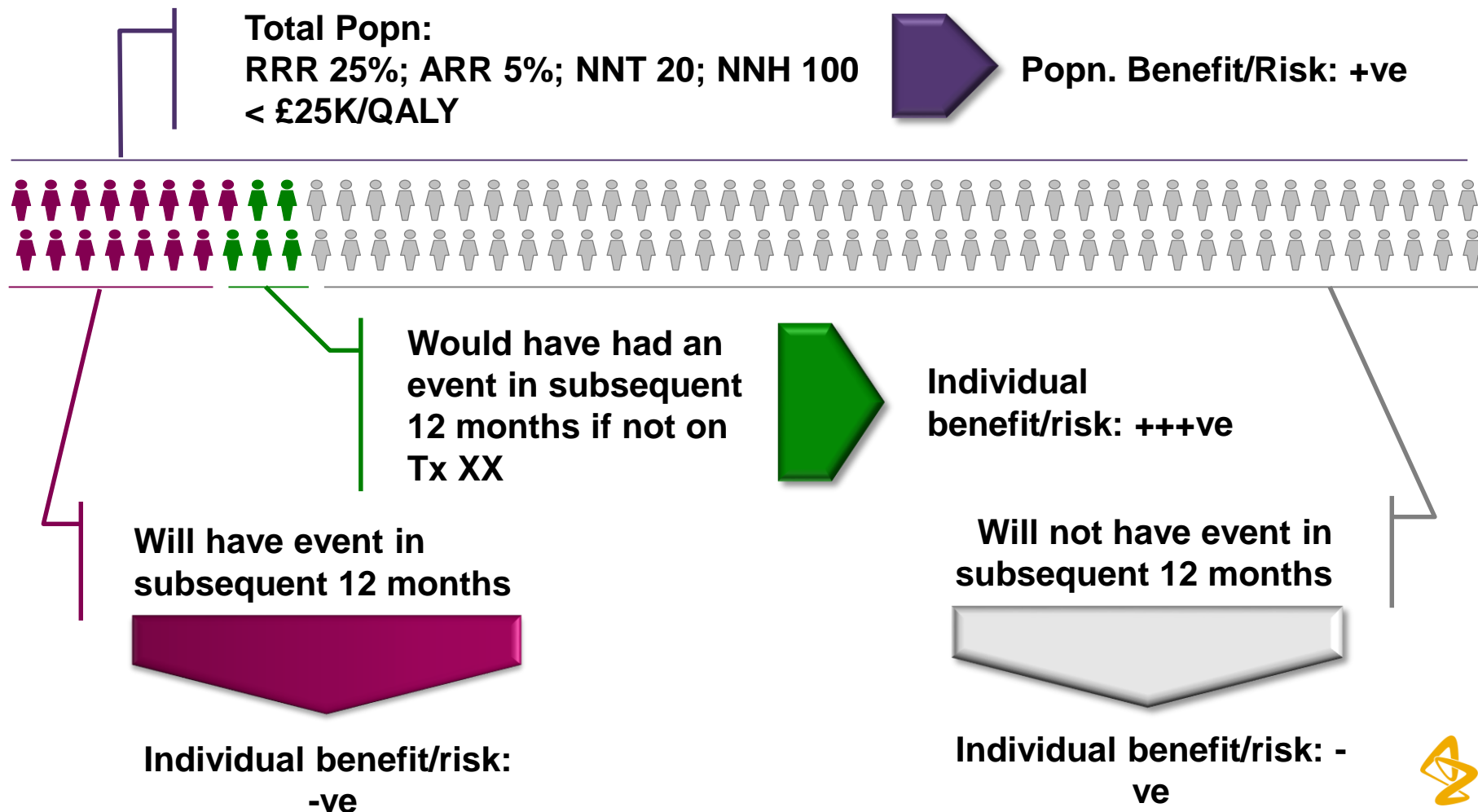
Influencing clinical development | understanding diversity

RWE ● ● ●



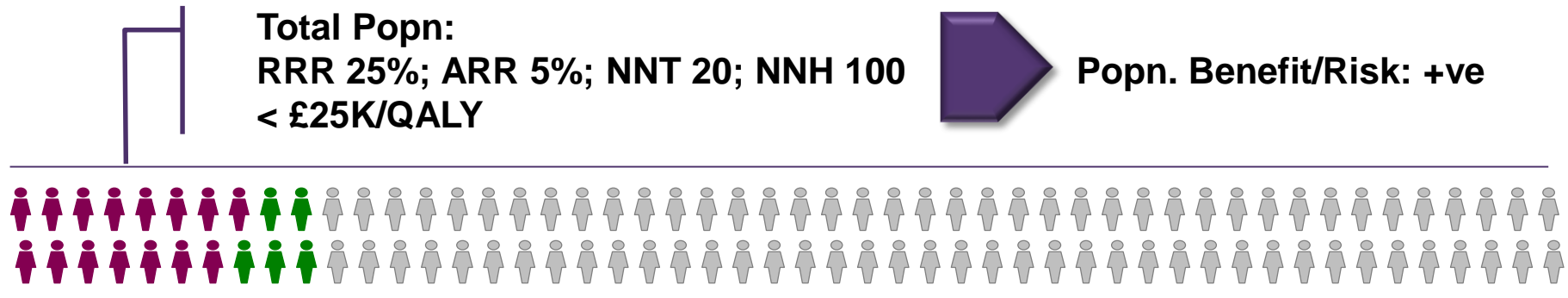
Personalising Healthcare

Population vs. patient level risk/benefit



Personalising Healthcare

Can RWE help in designing clinical trials and clinical pathways?



- Current treatment patterns (eg site/region of care, prior treatment, concomitant medications, use of other interventions, compliance...)
- Patient characteristics (eg. Comorbidity(ies), age, gender...)
- Disease characteristics and severity
- Diagnostic and laboratory markers (inc. baseline and kinetic variables)
- Care management (frequency of follow up, integration of medical team, schedule of assessments)
- Economic incentives/barriers (patient, pharmacy, hospital, national ...)

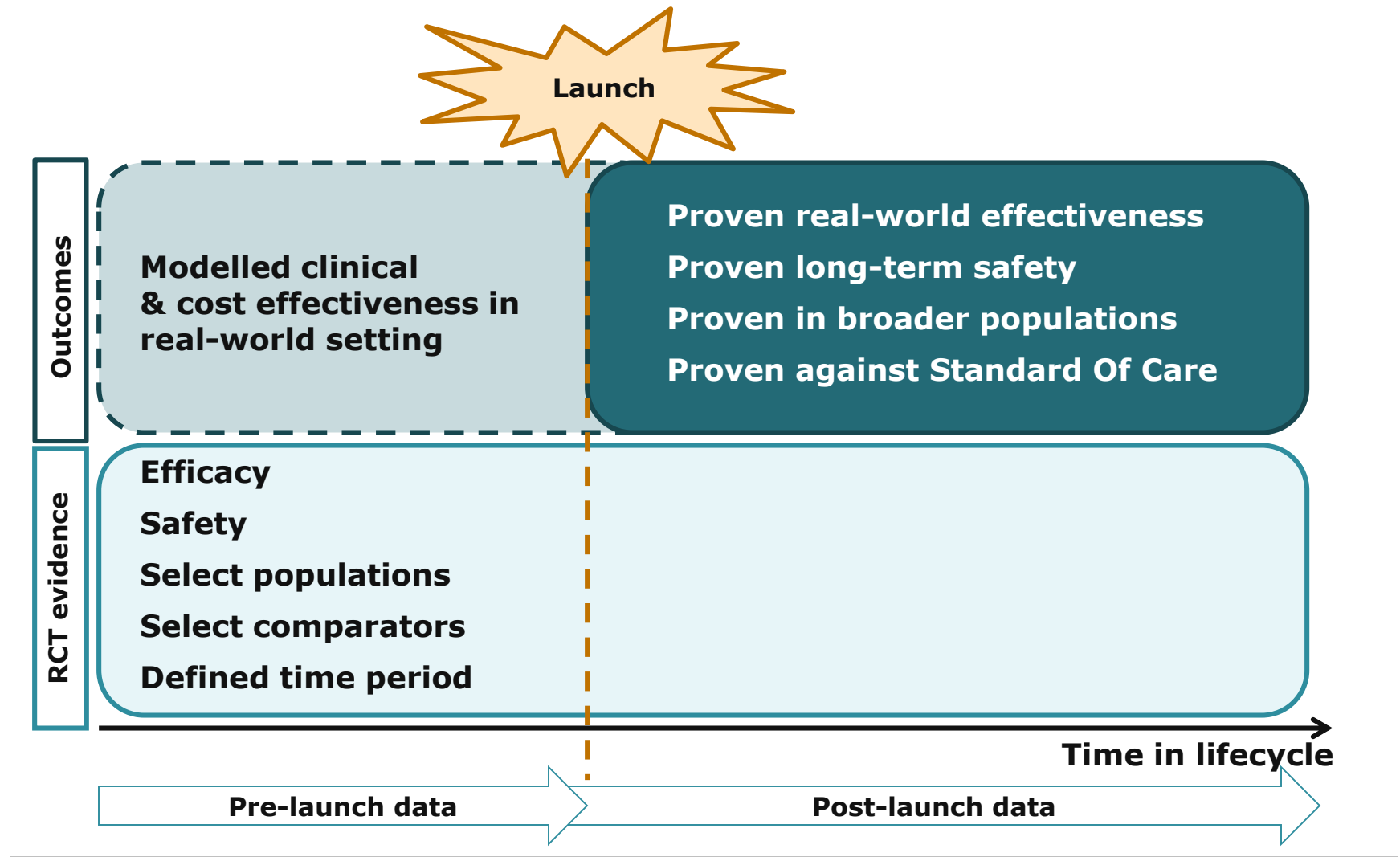


Managing uncertainty | claim validation

RWE ● ● ●



Real-world data enables continued scrutiny and evidence generation



RCTs and Real World Effectiveness

Registry data provide assurance that Avastin outcomes in mCRC RCTs are generalisable to real world



Bevacizumab plus Irinotecan, Fluorouracil, and Leucovorin for Metastatic Colorectal Cancer

Herbert Hurwitz, M.D., Louis Fehrenbacher, M.D., William Novotny, M.D., Thomas Cartwright, M.D., John Hainsworth, M.D., William Heim, M.D., Jordan Berlin, M.D., Ari Baron, M.D., Susan Griffing, B.S., Eric Holmgren, Ph.D., Napoleone Ferrara, M.D., Gwen Frye, M.D., Beth Rogers, B.S., Robert Ross, M.D., and Fairooz Kabbinavar, M.D.

Table 3. Analysis of Efficacy.*

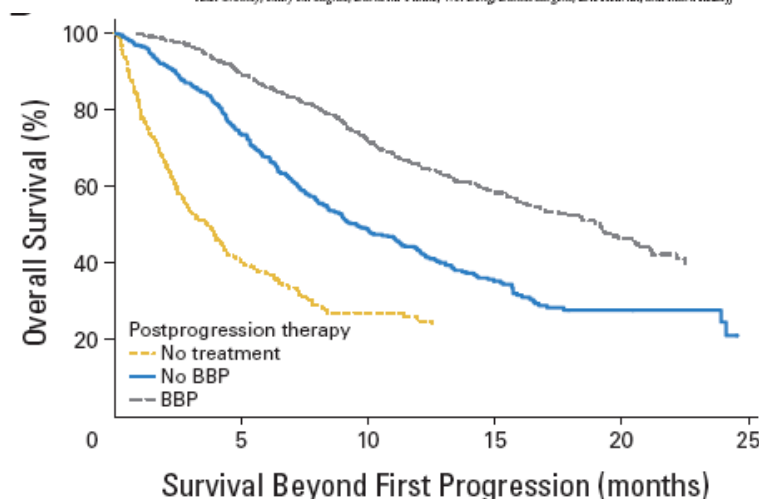
End Point	IFL plus Placebo	IFL plus Bevacizumab	P Value
Median survival (mo)	15.6	20.3	<0.001
Hazard ratio for death		0.65	
One-year survival rate (%)	63.4	74.3	<0.001
Progression-free survival (mo)	6.2	10.6	<0.001
Hazard ratio for progression		0.54	
Overall response rate (%)	34.8	44.8	0.004
Complete response	2.2	3.7	
Partial response	32.6	41.0	
Median duration of response (mo)	7.1	10.4	0.001
Hazard ratio for relapse		0.62	

* IFL denotes irinotecan, fluorouracil, and leucovorin.

JOURNAL OF CLINICAL ONCOLOGY ORIGINAL REPORT

Bevacizumab Beyond First Progression Is Associated With Prolonged Overall Survival in Metastatic Colorectal Cancer: Results From a Large Observational Cohort Study (BRiTE)

Axel Grothey, Mary M. Sugrue, David M. Punt, Wei Dong, Daniel Sargent, Eric Hedrick, and Mark Kozloff



	All patients (N = 1,953)	No post- progression treatment (n = 253)	No BBP (n = 531)	BBP (n = 642)
Number of deaths	932	168	305	260
Percent	47.7	66.4	57.8	40.5
1-year survival rate, %	74.7	52.5	77.3	87.7
95% CI	72.7 to 76.7	46.2 to 58.8	73.7 to 80.9	85.2 to 90.3
Median survival beyond first progression, months	10.9	3.6	9.5	16.8
95% CI	11.1 to 13.3	2.7 to 4.3	8.4 to 11.2	16.8 to 20.7

Improving value | the learning healthcare system

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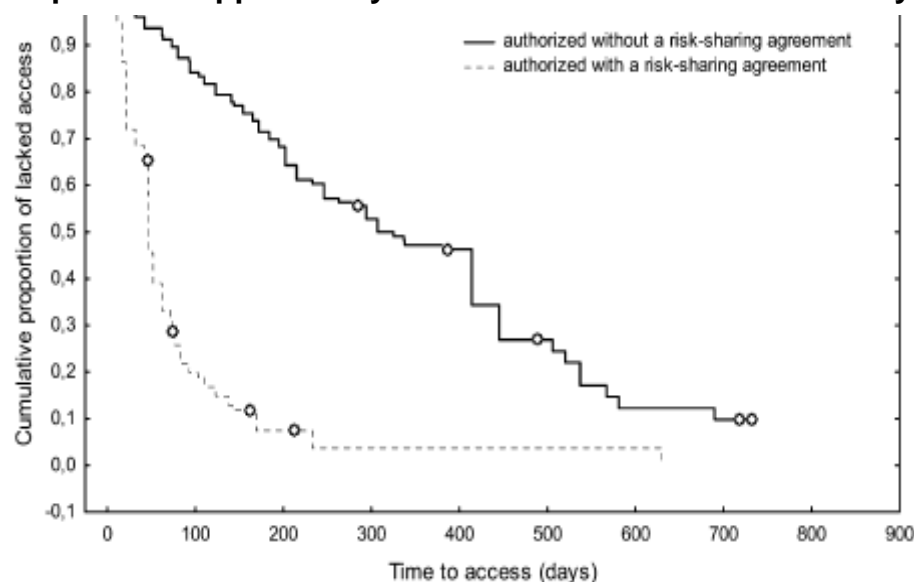


Italian (AIFA) Specialty Product Registry

Pay 4 Performance schemes have managed utilization and driven timely access of high cost oncology therapeutics



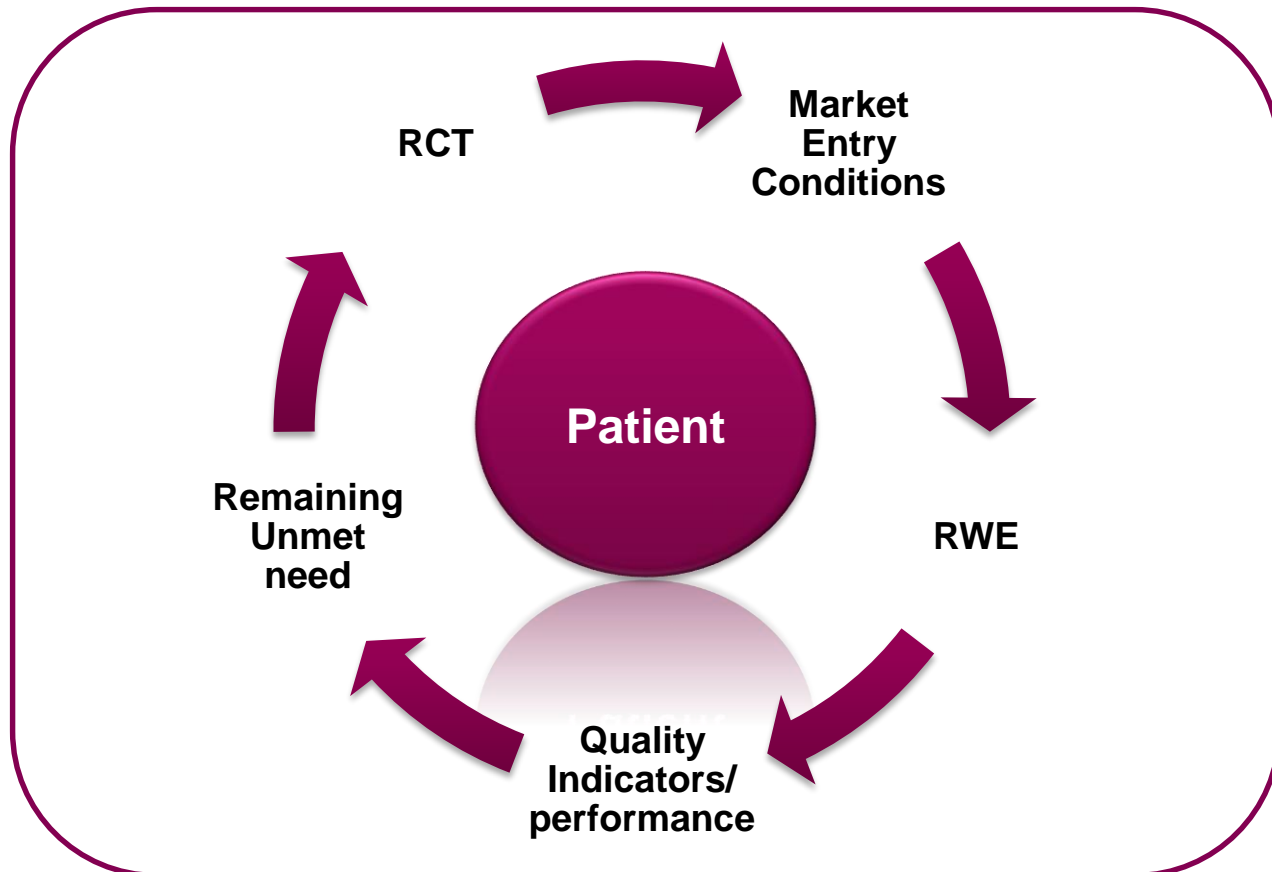
Kaplan–Meier curve of regional patient access to oncology products approved by the EMA from 2006 to 2008 in Italy



“Time to market and patient access to new oncology products in Italy: a multistep pathway from European context to regional health care providers,” P. Russo, F. S. Mennini, P. D. Siviero & G. Rasi, *Annals of Oncology*, March 24, 2010



Towards a learning healthcare system...

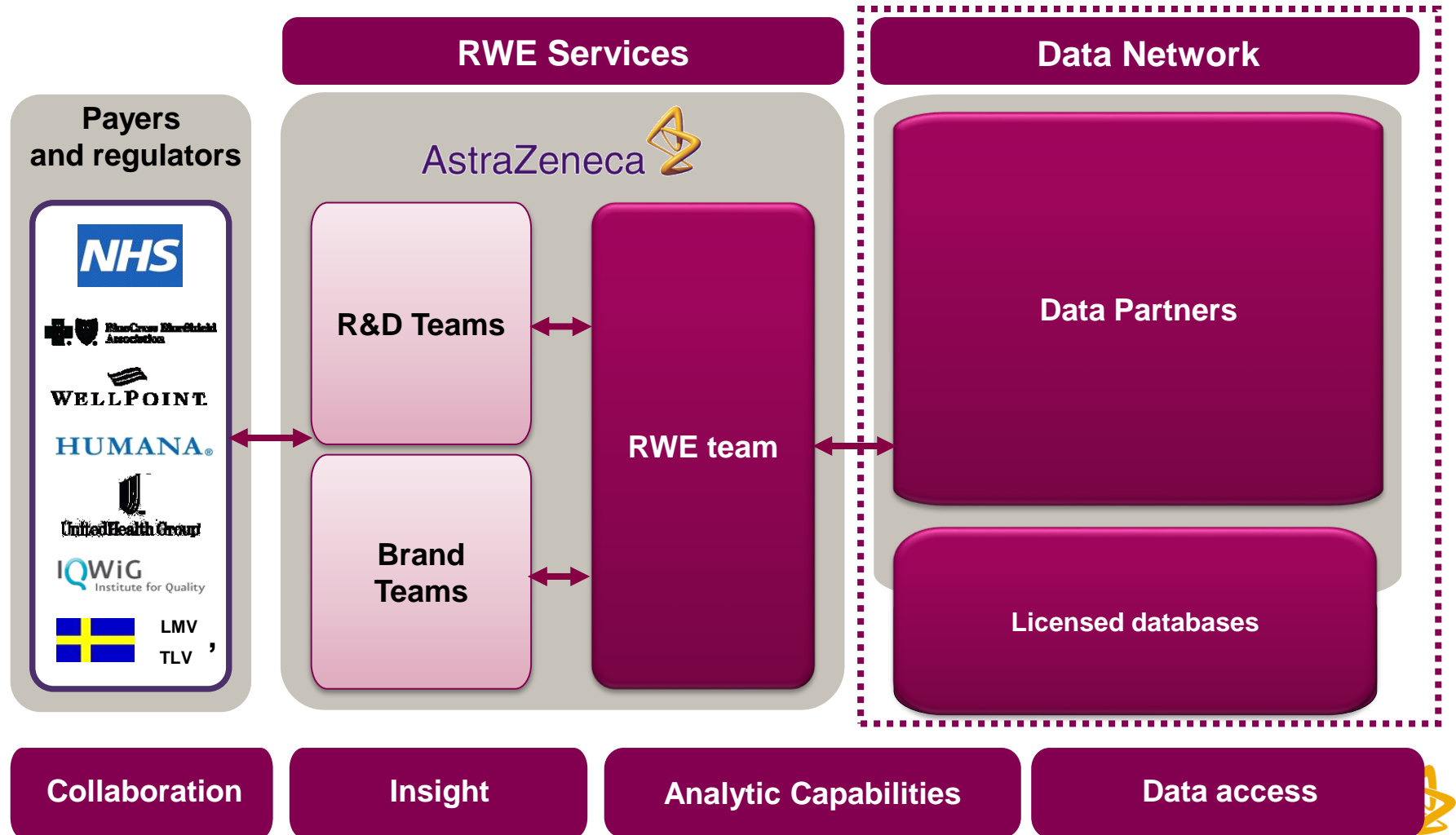


So what's AZ doing about it?

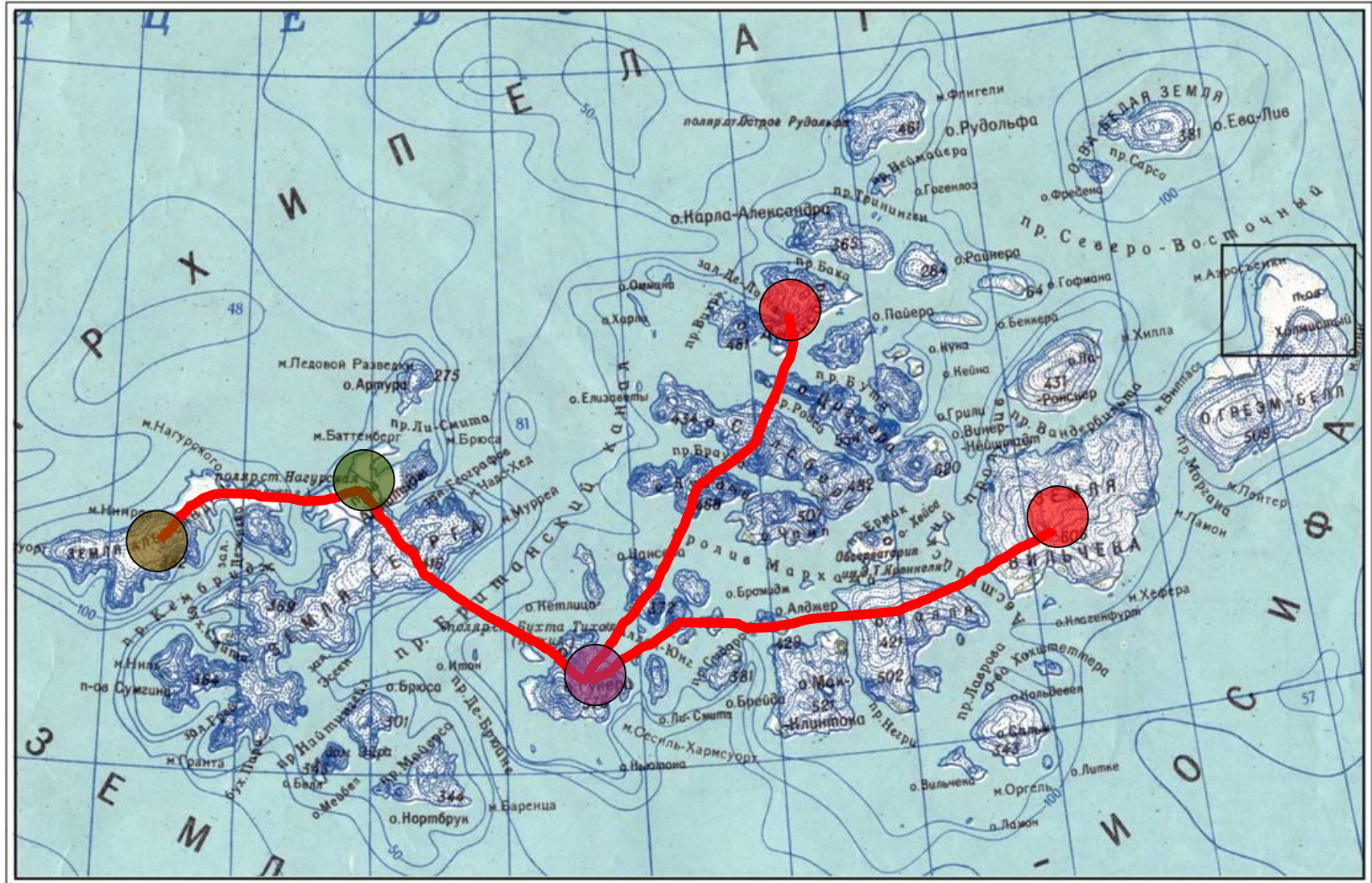
RWE ● ● ●



AZ has created an RWE skills centre to combine our expertise with the best in industry data partners

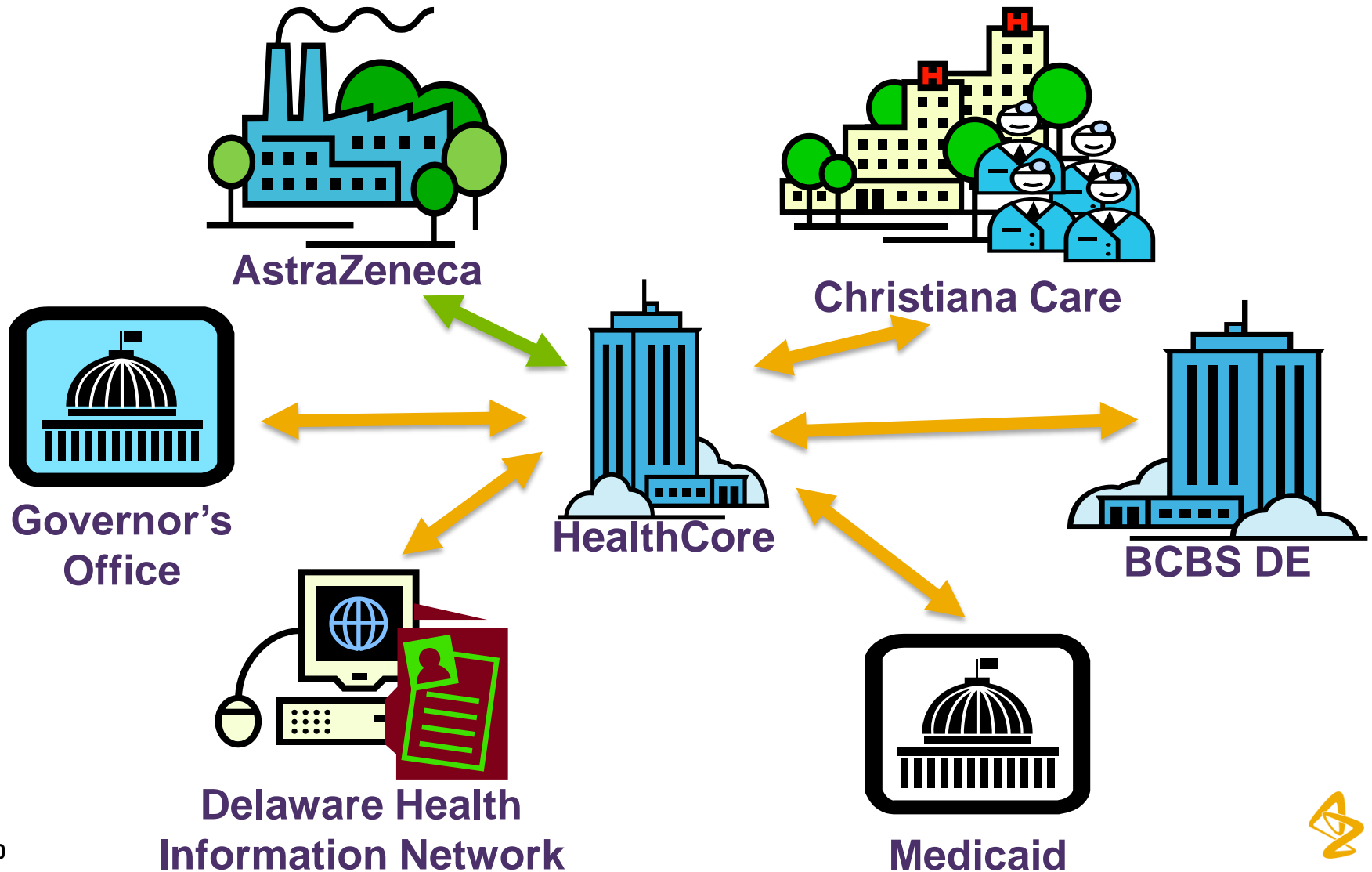


Creating a network of health data



A working example

Delaware state 'Enlightened Community'



AZ's Real World Evidence Capability has a global footprint

RWE goals



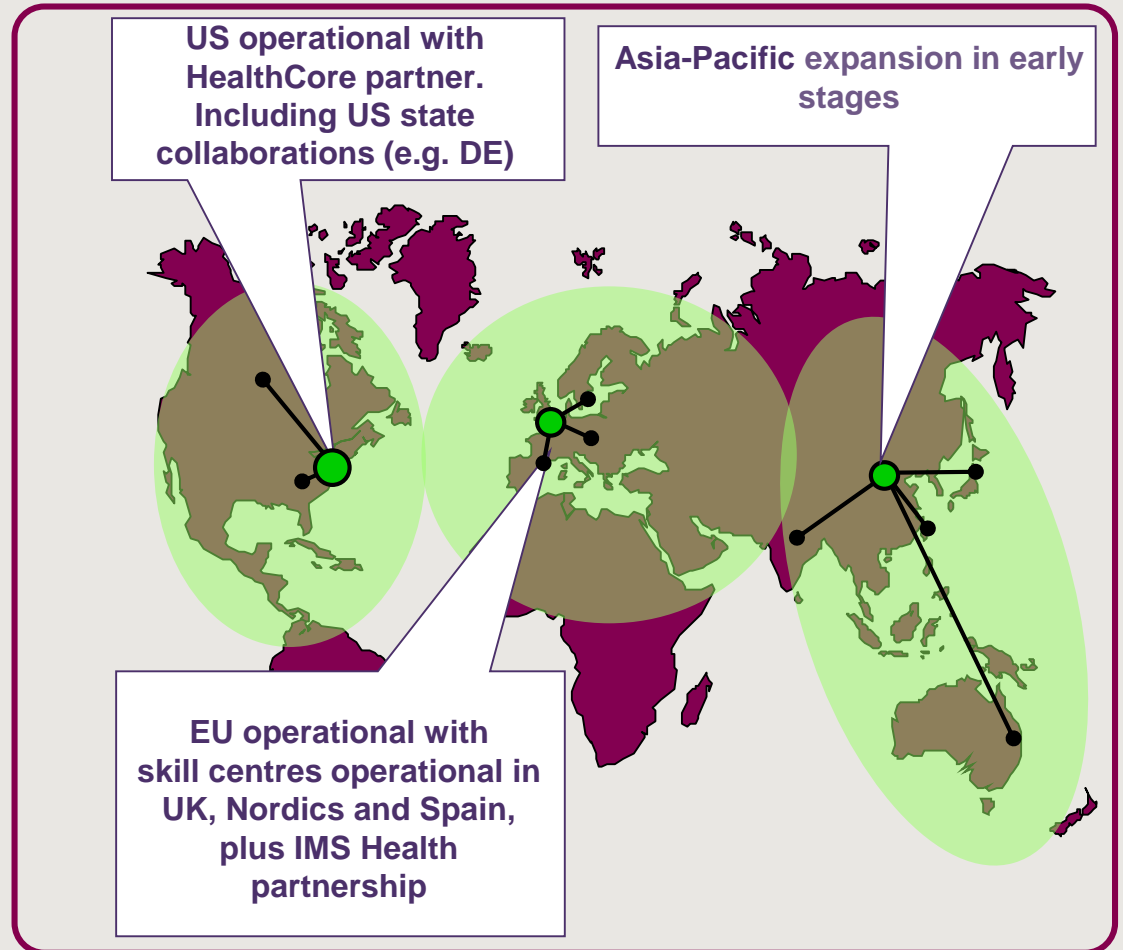
Access and integrate data based on business and Payer needs



Optimise analytics through the provision of innovate tools and methods



Improve credibility through information integrity and best practices



Four key enablers determine the pace and shape of RWE evolution



Robin Gibb

1949 - 2012

The family of Robin Gibb, of the Bee Gees, announce with great sadness that Robin passed away on Sunday 20 May, 2012 at 10:46pm following his long battle with cancer and intestinal surgery. They have asked that their privacy is respected at this very difficult time.

If you would like to send your respects or share your memories of Robin you can do so on the [comments page](#).

Thank you.

