Do we agree on when we need outcomes based agreements?

Vancouver, IHE Innovative Approaches to Industry-Payer Agreements: National Roundtable

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Brian Cuffel, Ph.D., Senior Director Global Market Access, Pfizer

Disclaimer

The views and opinions of the presenter are not necessarily reflecting the position of Pfizer.

The references in this presentation are reflective of a US environment. The purpose being to share learnings as Canada reflects on these partnerships

Some Observations

- **Observations:**
  - Arrangements seem to be useful in situations where there is uncertainty around financial and/or patient outcomes
  - More popular in Europe than in North America
- **Hypotheses:**
  - Risk sharing and innovative contracting arrangements are an attempt to reward outcomes rather than inputs in healthcare
  - They offer more flexible contractual arrangements in jurisdictions where traditional contracting is not possible or sufficient, eg Europe
  - Increases likelihood of achieving a price that reflects value in routine practice
- **Selected Unknowns**
  - Which is more important? Agreeing to reduce the uncertainty or agreeing on a formal risk-sharing agreement?
  - Does a contractual link between payment and outcomes align incentives?

Key Elements of An Outcomes Based Agreement

Which is More Important and Which Faces the Greatest Barriers?

Element*	Purpose	Potential Barrier
Agreement about a program of data collection	Reduce Uncertainty	◆ Cost and practicality of post-launch evidence collection ◆ Burden and time required to obtain good evidence ◆ Quality of the evidence and skepticism regarding the results generated
Price and/or revenue is linked (prospectively or retrospectively) by a formula to the results of this data collection program	Contractually Links Payment & Performance	◆ Risk aversion on part of payers and manufacturers ◆ Legal, regulatory, and policy issues

*Towse & Garrison. Can't get no satisfaction? Will pay for performance help? Toward an economic framework for understanding performance based risk-sharing agreements for innovative medical products. Pharmacoeconomics 2010; 28; 93-102.

Is Cost or Complexity a Barrier to An Outcomes-Based Agreement?

Uncommon Biopharmaceutical Risk-Sharing Arrangement

Merck-Cigna Diabetes Agreement

- Reductions in HBA1C increases discounts by Merck
- Increased adherence increases discounts by Merck

Agreements such as that Between Merck and Cigna Less Complicated than More Common Agreements Adopted by US Health Insurers

Common Disease Management Risk-Sharing Arrangement

Illustrative Example

- Rate of diabetic retinal screening
- Rate of HbA1C testing
- Rate of HbA1C poorly controlled (> 9.5%)
- Rate of LD-C screening
- Rate of LDL-C control (LDL < 130 mg/dL)
- Rate of screening for diabetic kidney involvement (nephropathy)
- Flu vaccination rates
- Pneumovax immunization rates
- Diabetes ER Visits / 1000
- Acute hospital admissions / 1000

Medical Cost Savings Guarantee Expressed as a Percentage. Calculated within Age and Risk Bands:

[(A*F-B-C)/ (A*F)] * 100

A = Baseline Year

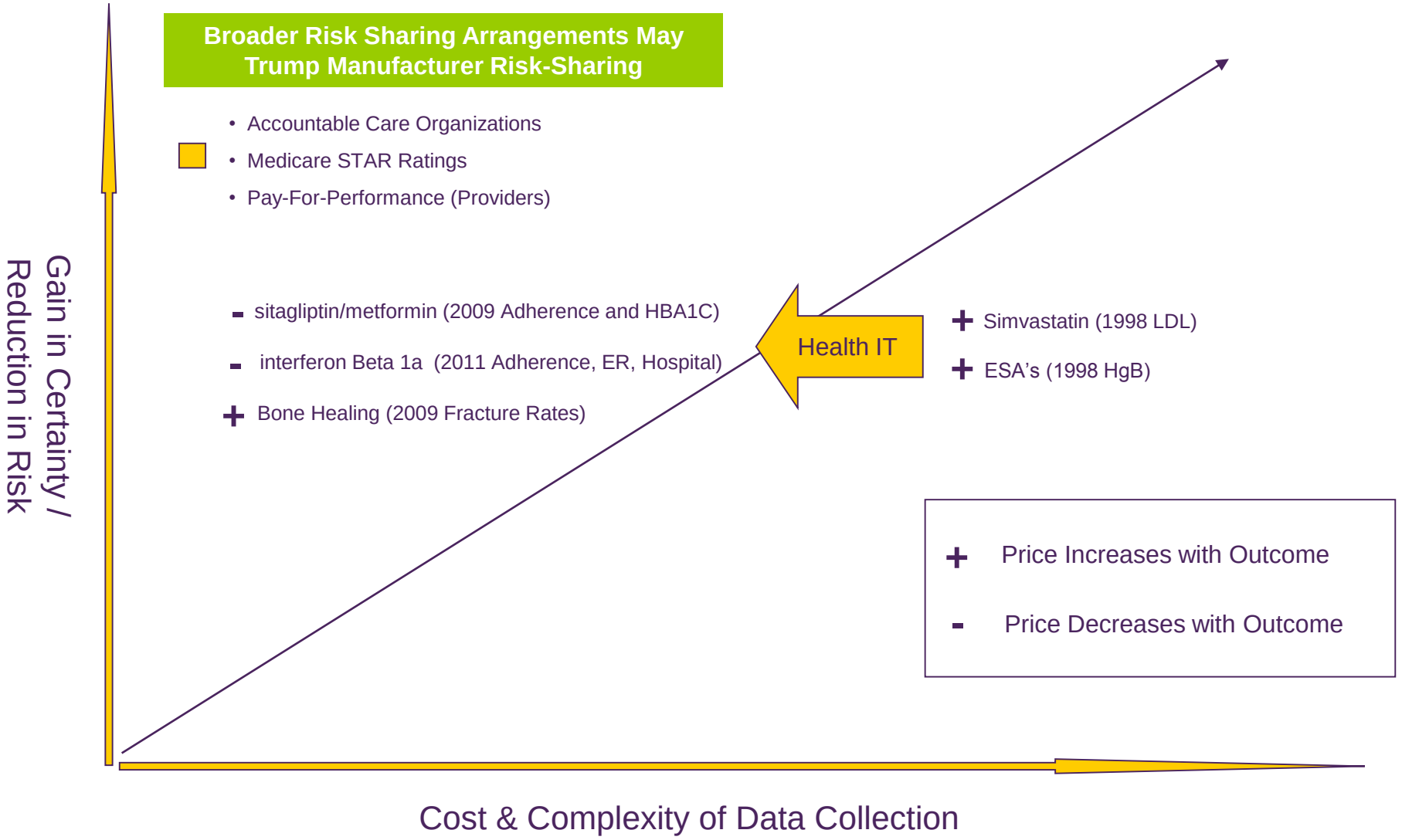
B = Measurement Year

C = Fees Paid

E = Medical Cost Trend, compounded annually

F = 1+E

Differences in Price-Outcome Relationship Raises Questions about Incentives in Outcomes Agreements for Biopharmaceuticals



Pfizer Primary Care

Contracting Incentives in the US

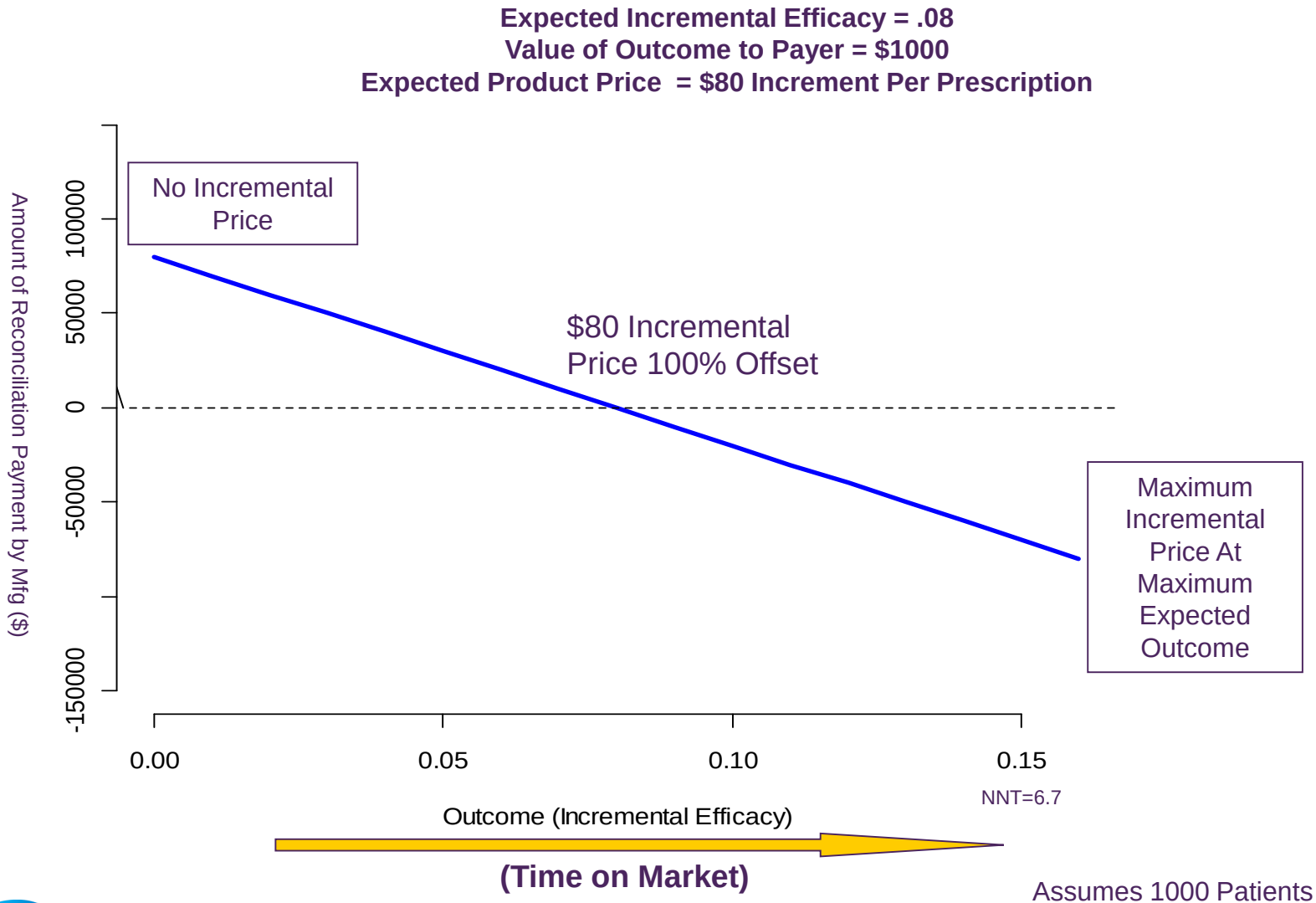
	Drug Price & Utilization Relationship	*Drug Price & Outcome Relationship*	*Payer Tools*
No Contract	*NA*	*NA*	NA
Traditional Contract	—		◆ Benefit / Coverage ◆ Formulary Incentives ◆ Utilization Management
Outcomes Contract	+ *or* -	+ *or* -	◆ Benefit / Coverage ◆ Formulary Incentives ◆ Utilization Management ◆ Disease Management ◆ Outreach / Patient Engagement

\+ Manufacturer sets higher price for better outcome (Pay for performance)

\- Manufacturer sets lower price for better outcome (Discount for performance)

"… an outcomes contract that lowers the price on a product if an outcome is achieved is only aligned with the payer's interest if the baseline is ignored or already accepted due to market dynamics / level of control …" Pharmacy Director, National US Health Insurer

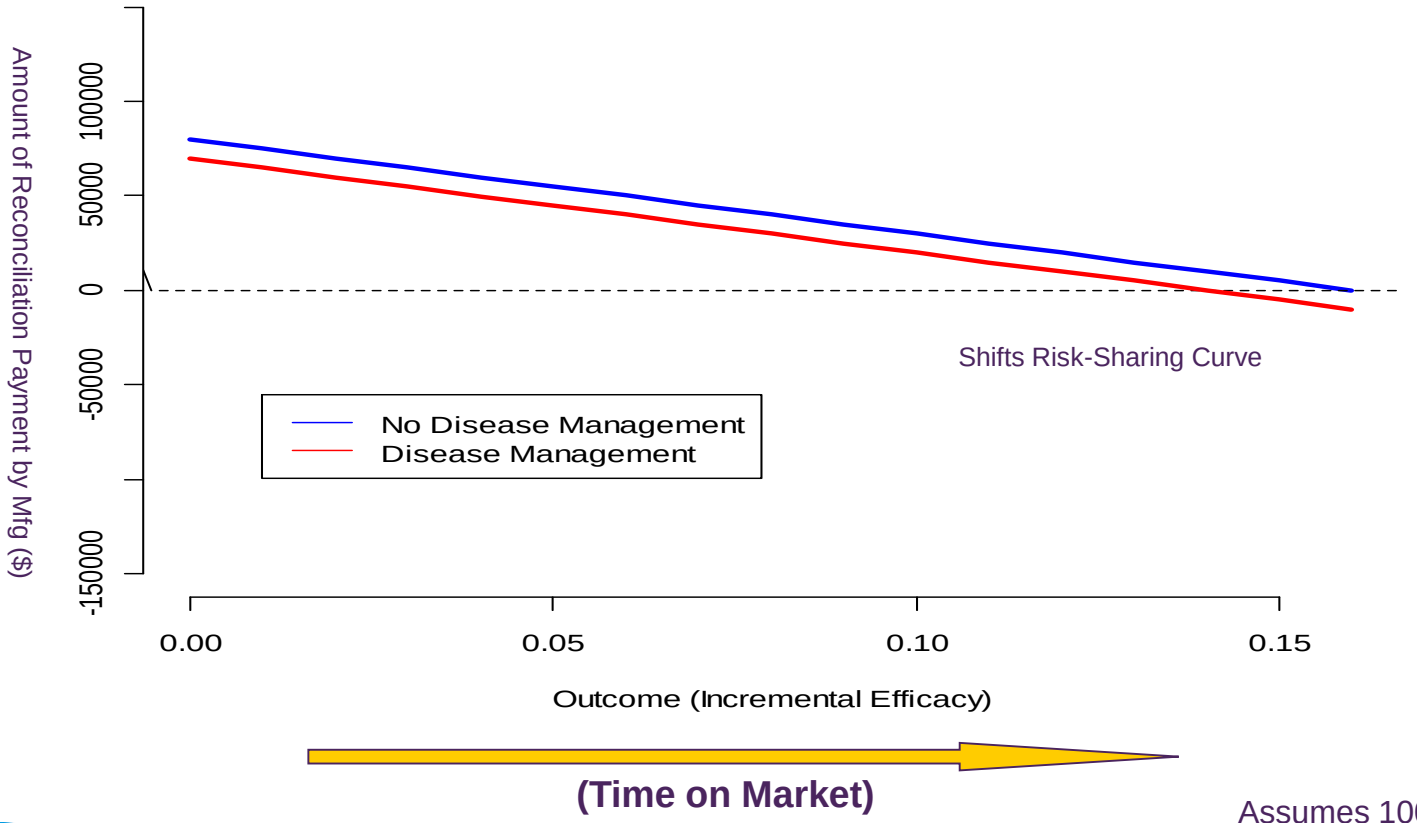
Simple Pay for Performance Scenario



Assumes 1000 Patients and 10 Rx Per Patient

Does Contracting for Outcomes Give Payers Incentives to Improve Disease Management?

Disease Management Increases Outcomes & Costs by 25% Relative to Drug
Incremental Efficacy = .08
Expected Product Price = $80 Increment Per Prescription
Value of Outcome to Payer = $1000



Assumes 1000 Patients and 10 Rx Per Patient

Potential Disincentive for Payers in Pay for Performance Scenario

Outcomes Raise the Effective Drug Price for Manufacturers And Savings Offset Incremental Drug Cost for Payers

Incremental Efficacy	Justifiable Drug Price	Incremental Drug Cost	Incremental DM Cost	Incremental Benefit	Savings Due to Improved Outcomes	ICER
Baseline (0%)	$ -	$ -	$ -	0	$ -	
Expected (8%)	$ 80	$ 80,000	$ -	80	$ 80,000	$ -
Upside (16%)	$ 160	$ 160,000	$ -	160	$ 160,000	$ -

Disease Management Improves Outcomes and Total Savings But Reduces Overall Cost-Effectiveness

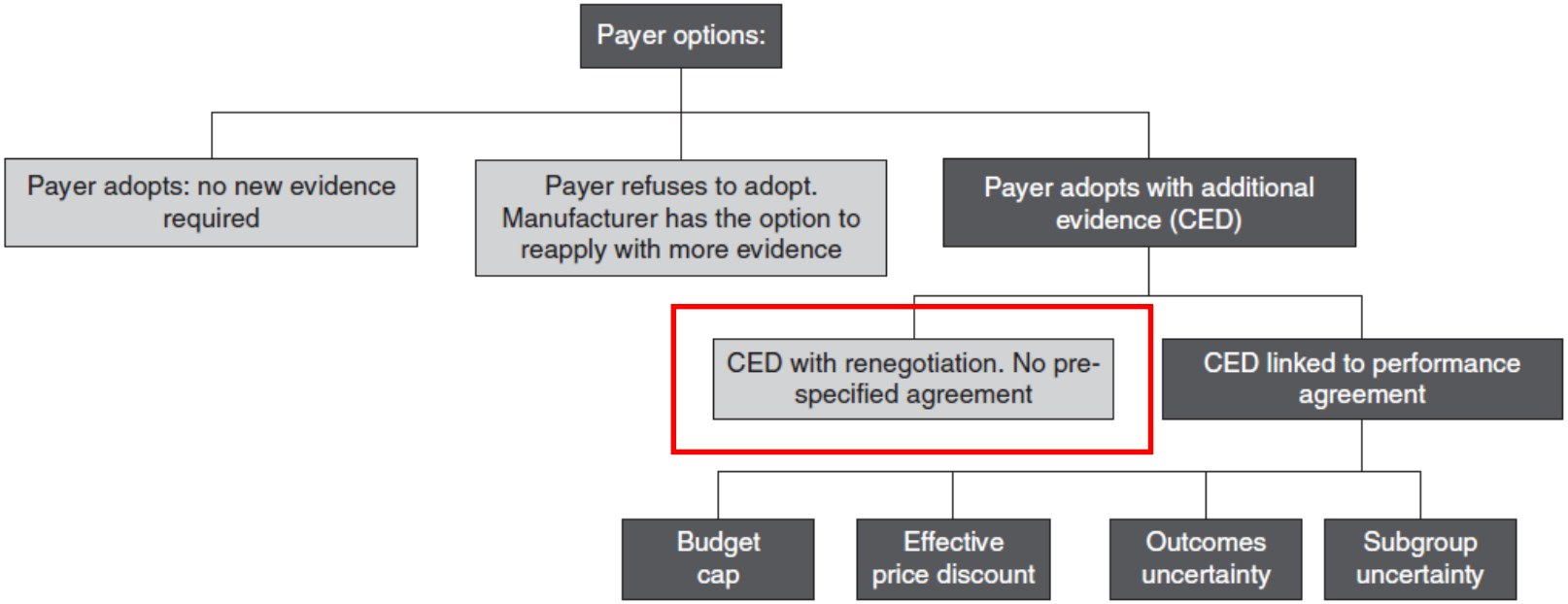
Incremental Efficacy	Justifiable Drug Price	Incremental Drug Cost	Incremental DM Cost	Incremental Benefit	Savings Due to Improved Outcomes	ICER
Baseline (0%)	$ 20	$ 20,000	$ 20,000	20	$ 20,000	$1,000
Expected (8%)	$ 100	$ 100,000	$ 20,000	100	$ 100,000	$ 200
Upside (16%)	$ 180	$ 180,000	$ 20,000	180	$ 180,000	$ 111

Additional Implications:

- Payers give a drug premium when incremental efficacy is 0%
- Cost-effectiveness from a payer perspective is lowered by the intervention
- Patients are the primary beneficiaries of this arrangement
- Manufacturers may benefit if disease management increases use of drug relative to more restricted scenarios

Payer Decisions Under Uncertainty

US Payers Trending Towards Rarely Considered Option



Source: Towse & Garrison. Can't get no satisfaction? Will pay for performance help? Toward an economic framework for understanding performance based risk-sharing agreements for innovative medical products. Pharmacoeconomics 2010; 28; 93-102.

Changes in US environment addressing uncertainty regarding real world costs and benefits

Advancing Health Information Technology

- US Stimulus funding. ARRA will provide $37B in incentives for “meaningful use” of electronic health records and penalties for non-use in 2015
- $2B for infrastructure allowing exchange of records among provider systems
- Affordable Care Act will establish new “business-to-consumer” IT capabilities

Investment in Outcomes Research

- Largest US insurers and PBMs are growing their consulting services and opening discussions regarding benefit and formulary decision makers notably Wellpoint (Healthcore), United (I3), Humana, Medco (recently acquired UBC)
- Other national payers such as Aetna and CVS Caremark are developing internal Outcomes Research capabilities. ESI has an established, internal OR group

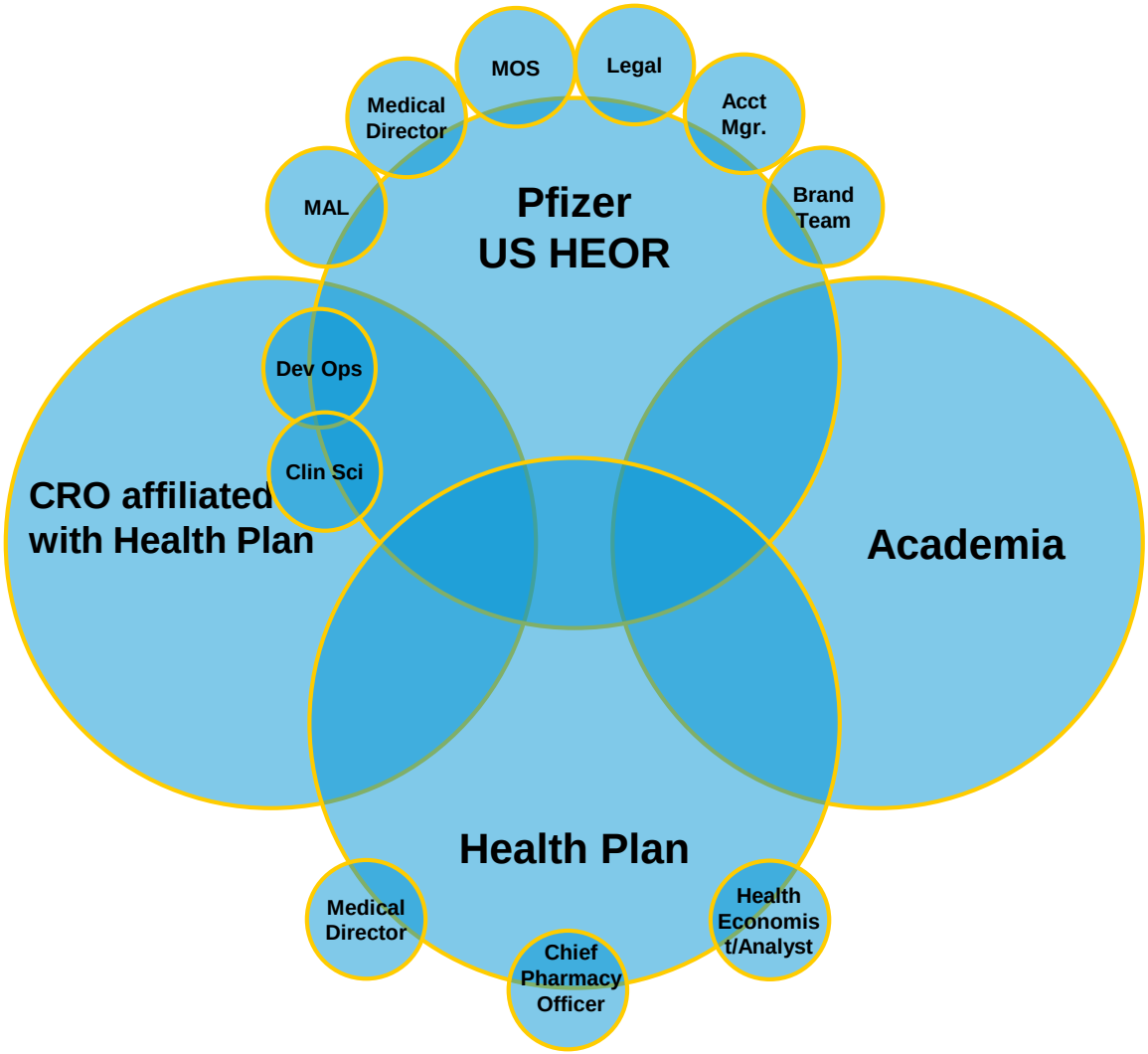
Comparative Effectiveness

- Increasing recognition of the need for H2H data
- Affordable Care Act establishes Patient Centered Outcomes Research Institute (PCORI)
- Largest US MCO published comparative effectiveness guidelines for manufacturers in 2010

Payer Activism

- Most comparative data published in top tier journals s generated by non-industry sources (Hochman et al. JAMA, 2010).
- Payers challenge the credibility of industry sponsored research. Regence publishes report indicating that 9% of industry sponsored studies are “reliable”
- Increasing direct involvement in “real-world”, comparative analyses (e.g., Wellpoint analysis of Fibro drugs, Antipsychotics, Asthma Treatments)

Pfizer outcomes research increasingly looks like ….



Ex-Ante and Ex-Post Reductions in Uncertainty

"Ex-Ante" Reductions in Uncertainty

- Early Scientific Engagements
  - New global opportunities (UK, CA, SE, AU)
  - US opportunity for collaboration starting in early development
- Greater focus by manufacturers on payer evidence requirements and incorporating into Phase III programs
- Starting Phase IV in Phase III (e.g. trials examining return-to-work and other real-world outcomes)
- Convergence of Payer and Regulatory Evidence Requirements in HTA markets

"Ex-Post" Reduction in Uncertainty

- Joint collaboration around evidence development (independent of contractual arrangements)
- US Payers engaging in real world data studies and incorporating into their formulary decisions
- Advances in HIT accelerates evidence generation and reduces the time required to evaluate real world costs and benefits
- B2B opportunities for open and transparent collaboration regarding evidence generation

Hypothesis: Confidence in Ex-Ante and Ex-Post Mechanisms and Capabilities Reduces Need for Special Arrangements at Market Entry

Looking Forward

- **Special contracts linking price to evidence generated outcomes will continue to be exceptions and in areas where incentives can be aligned**
- **Health care systems look for broader risk sharing arrangements that affect a greater number of health care cost drivers than narrower agreements with manufacturers**
- **Uncertainty regarding clinical and financial outcomes is a critical issue affecting reimbursement decisions but the emphasis is on finding credible ways of reducing that uncertainty**
- **Skepticism regarding the quality of evidence generated from performance agreements relative to evidence generated from controlled retrospective and prospective sources**
- **Open and transparent partnerships regarding real world evidence generation will further enable - "CED with renegotiation. No pre-specified agreement" owing to:**
  - Need to reduce costs and maintain or improve quality of health care
  - Cost of evidence generation is reducing
  - Path of least resistance