THIRD PLENARY:
Risk Sharing Agreements: Country Experiences, Challenges, and Lessons Learned

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RISK SHARE AGREEMENTS

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September 11, 2018
Plenary Session
ISPOR Asia, Tokyo

Disclaimer

The speaker is an employee of Pfizer Inc. Views and opinions expressed are the speaker's own and do not necessarily reflect those of the company.

Agenda

Healthcare environment
Risk share agreements: definition, types and pre-requisites
Experience with risk-share agreements
Where should we go now?

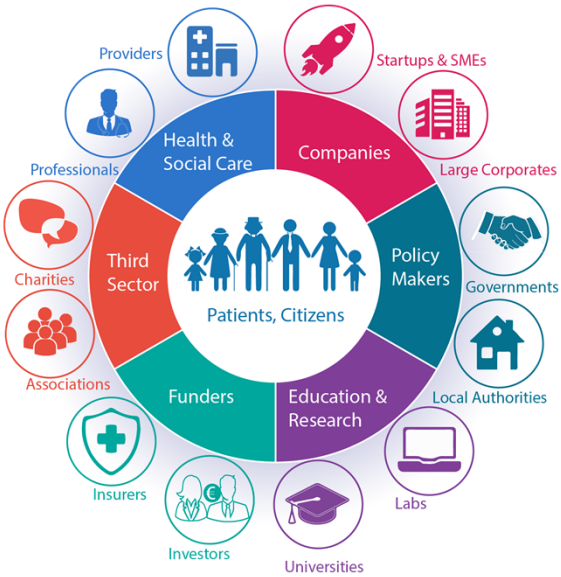
Drivers of Risk-Share Agreements for Medicines

Innovative Medicines & Budget Pressure

Requirements for health outcomes

Digital capture of health data

The Digital Health Ecosystem



1. **ECHAlliance International Connected Health Ecosystem Network:** https://echalliance.com/events/EventDetails.aspx?id=1068834

Healthcare environment is evolving: blockchain technology

June 2018: Walmart Just Scored a Patent for a Blockchain-Based Health Care Records System[1]: To allow first responders to pull up medical data from a patient in the case of an emergency when he or she can't communicate

Walmart

"This system would depend on a wearable device which houses the actual patient data (on a blockchain).

Another device, a biometric scanner, in conjunction with an RFID scanner, would be used to identify and then unlock the medical data stored on the wearable device.

Two separate digital keys, one private and one public, would be at play, with the private key decrypted by scanning a major biometric feature of the patient (say, a retina image or fingerprint)."

1. http://fortune.com/2018/06/22/walmart-blockchain-patent-health-records/

Healthcare environment is evolving: Asia's digital giants

July 2018: Alibaba v. Tencent: The Battle for Supremacy in China[1]

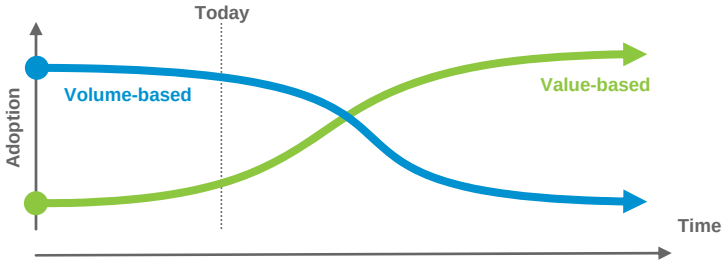
Alibaba Group

Tencent 腾讯

"Both companies touch an astounding percentage of the world's most populous country: Alibaba's various online marketplaces count **552 million active customers**; Tencent's WeChat messaging service recently surpassed **1 billion accounts**"[1]

1. http://fortune.com/longform/alibaba-tencent-china-internet//

The healthcare marketplace will change rapidly



	From a UTILIZATION Marketplace…	…To an IMPACT Marketplace
Patients	• Limited access to health data	• Seamless integration of technology
Society / Systems	• Contracting based on volume • Pricing per pill	• Transition to value based pricing model • Targeted populations
Pharma	• Rx based revenue model	• Health solutions oriented • More trust-based partnerships • Increased investment in data & technology

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- Healthcare environment
- **Risk share agreements: definition, types and pre-requisites**
- Experience with risk-share agreements
- Where should we go now?

Value-based (risk-share) agreements in healthcare

To support the move to value-based care and be committed to the goals of improving the quality and outcomes of care delivered to patients while optimizing overall healthcare costs.

For this presentation

Value-based agreements = **Risk-share agreements**

What are Risk-Sharing Agreements (RSA)?

RSAs for approved medicines are performance based contracts between a manufacturer and an insurer or specialized government agency

- **Common goal**: provide timely access to innovative medicines by reducing uncertainty of either financial or clinical nature
- **Include performance based considerations**: could be financial and/or outcomes-based
- **Performance Metric:** should be easily identifiable and measurable
- **Data collection infrastructure**: there has to be a verified and current mechanism to collect data points measured in the contract
- **Risk:** both the manufacturer and the insurer have to take on risk
- **Patients**: the contract has to create value to patients
- **Result:** might not always lead to reduced costs, but to optimized costs and outcomes

Types of Risk Share Agreements for Pharmaceuticals

Terms	Description	Examples
Financial-Based Agreements	Price level or nature of reimbursement is based on financial considerations and is not related to clinical performance	Price-volume agreements Total cost cap Non-price discounts/ free goods
Outcomes-Based Agreements	Price level or nature of reimbursement is tied to future metrics ultimately related to patient performance, outcomes, efficacy, tolerability, dosing, benefit, outcomes, quality of life, or clinical usage	Outcomes guarantee Compliance monitoring Pattern or process of care
Coverage with Evidence Development (CED)	Reimbursement decision in which approval is conditional on the collection of additional population level studies after launch (with provisional reimbursement) to support coverage or pricing	Centers for Medicare and Medicaid Services agreements around medical devices (US) Managed Entry Scheme (AUS)

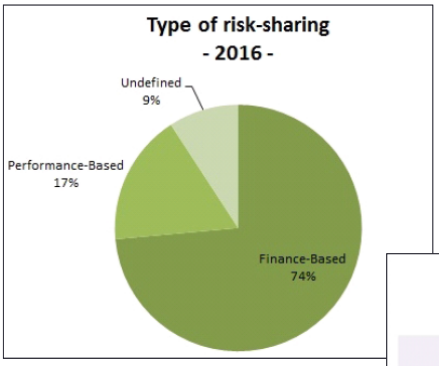
Network for Excellence in Health Innovation (US)

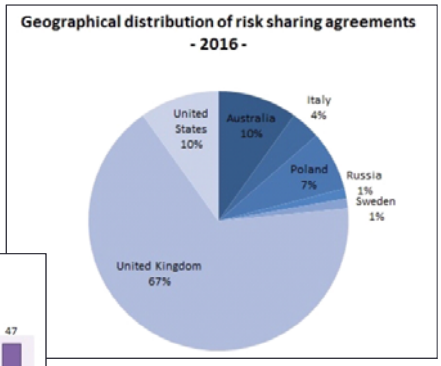
VBC in Oncology: 7 Recommendations

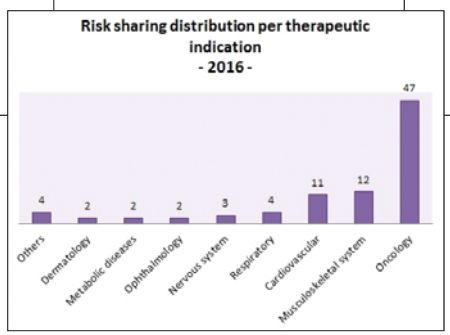
1. Payers, pharma, data collection organizations should address challenges in collecting and analyzing data to facilitate VBC
2. A cross-sectional group of stake-holders should develop a set of patient-centric and patient-reported measures for oncology care
3. FDA should finalize draft guidance on communication between payers, manufacturers and other entities
4. CMS should provide reasonable accommodation for Government Best Price and other reporting requirements
5. The Office of Inspector General in HHS should develop new safe harbors to the Anti-Kickback Statue to enable certain activities for VBC
6. The Office of Civil Rights in HHS should develop guidance on HIPPA compliance in the context of VBC
7. Stakeholders should continue discussion and investigation of new long-term financing approaches for high-cost therapies and cures

Network for Excellence in Health Innovation: https://www.nehi.net/publications/79-value-based-contracting-for-oncology-drugs-a-nehi-white-paper/view

Global trends for Risk Share Agreements







IHS Markit: RSA March 2018

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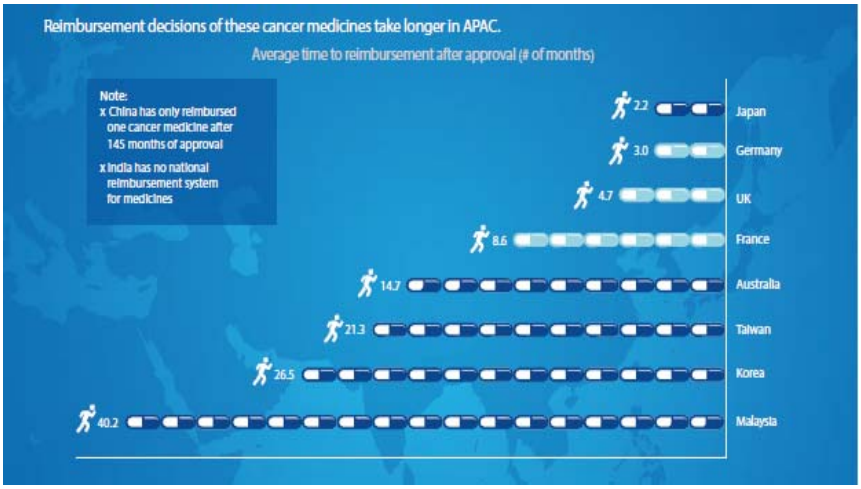
Situation: delayed time to access of new cancer medicines in some Asia – Pacific countries



Source: research conducted by IMS in 2017.

Managed Entry Schemes: The Australian Experience (1)

2010

Managed Entry Scheme (MES) Introduced by Australian Government to improve patient access

11

Drugs considered for MES 2010-17; 75% oncology Rx

3

MES established and implemented: crizotinib, trametinib, pembrolizumab

Tuffaha et al. Australian Managed Entry Scheme: Are we Getting It Right? PharmacoEconomics 2018

Managed Entry Schemes: The Australian Experience (2)

MES initiation: > 50% of proposal were made by pharma sponsors

Main uncertainty for oncology products with MES: overall survival benefit

MES components: PBAC determines the key uncertainty, the evidence required, the timeframe for submission of the evidence, and consequences

Drug listing while MES ongoing: If PBAC agrees to the MES, the drug is recommended for listing at an initial price based on the existing evidence

Price and listing after new MES evidence: PBAC may increase or decrease the initial price, amend or introduce restrictions on the use, or delist the drug

MES implementation: through a Deed of Agreement between the sponsor and the Australian Government. The DoA is a legal commercial contract

MES governance: the conditions governing MES should be clear, transparent, and balanced to address expectations of various stakeholders

Tuffaha et al. Australian Managed Entry Scheme: Are we Getting It Right? PharmacoEconomics 2018

Risk-Share Agreements in US: Few But Increasing

Drug	Manufacturer	Payer	Year Announced
Enbrel (etanercept)	Amgen	Harvard Pilgrim	2017
Forteo (teriparatide)	Eli Lilly	Harvard Pilgrim	2017
Januvia (sitagliptin) and Janumet (sitagliptin/metformin)	Merck	Aetna	2016
Trulicity (dulaglutide)	Lilly	Harvard Pilgrim	2016
Entresto (sacubitril/valsartan)	Novartis	Harvard Pilgrim	2016
Entresto	Novartis	Aetna	2016
Entresto	Novartis	Cigna	2016
Repatha (evolocumab)	Amgen	Cigna	2016
Praluent (alirocumab)	Sanofi, Regeneron	Cigna	2016
Iressa (gefitinib)	AstraZeneca	Express Scripts	2016
Repatha	Amgen	Harvard Pilgrim	2015
Repatha	Amgen	CVS Health	2015
Repatha	Amgen	Prime Therapeutics	2015
Harvoni (sofosbuvir/ledipasvir)	Gilead	Cigna	2015
Praluent (alirocumab)	Sanofi, Regeneron	Prime Therapeutics	2015
Viekira Pak (Dasabuvir, ombitasvir, paritaprevir and ritonavir)	Abbvie	Express Scripts	2015

- PhRMA reports approximately 40 publically available value-based agreements (Aug 2018)
- More agreements exists, but have not been announced publically
- 74 % of health insurance plans report seeing cost savings as a result of their value-based agreement
  - a significant increase compared with the 33 % reporting savings in 2017
- There are still important barriers to execution of such agreements

PhRMA: Barriers to value-Based Contracts for Innovative Medicines, March 2017
https://catalyst.phrma.org/number-of-value-based-contracts-continues-to-rise?utm_source=NPC+Contact+List&utm_campaign=5edde9f2fd-EMAIL_CAMPAIGN_2018_08_28_06_29_COPY_01&utm_medium=email&utm_term=0_3ddd3927eb-5edde9f2fd-245025309

Lung Cancer Outcomes-Based Agreement in US

Overcoming Challenges of Outcomes –Based Contracting For Pharmaceuticals: Early Lessons From The Genentech-Priority Health Pilot
Health Affairs, April 2017

- Avastin (bevacizumab) in patients with non–small-cell lung cancer
- Rebates tied to PFS, a key endpoint in the phase 3 RCT
  - The shorter the PFS in a given patient, the greater the rebate to Priority Health.
  - If PFS > 6 months (median PFS from ph3 RCT), Priority Health would not receive a rebate
- Measurement of PFS at the individual level
  - expedites data capture and increases the timeliness of rebates
  - methods for verifying PFS from claims, imaging, and electronic health record data
- Rebates calculated for each patient

Health Affairs Blog: http://healthaffairs.org.proxy1.athensams.net/blog/2017/04/03/overcoming-challenges-of-outcomes-based-contracting-for-pharmaceuticals-early-lessons-from-the-genentech-priority-health-pilot/

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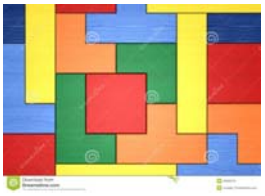
Key enablers of RSAs:

- Willingness of all parties to engage in innovative approaches
- Enabling regulations allowing for these complex transactions
- Patient privacy protection
- Infrastructure for timely and reliable data collection



Summary

Innovation in healthcare delivery, digitalization, advances in breakthrough medicines are significant drivers for finding new ways for patients to access medicines
Specialty medicines (oncology, gene therapies, etc) are becoming more complex causing high variability in approval and use in clinical practice
Risk share agreements for medicines are not very common as they are difficult to execute
Key enablers such as regulations for RSAs, patient privacy protection, and data collection infrastructure, need to be in place to facilitate broader use of RSAs