HTAi Workshop: Risk Sharing Agreements—a company perspective

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Workshop Goals: risk sharing among manufacturers, regulators, payers

1) Share information on the drive for regulatory and payer focused risk sharing
2) Outline a range of payer-focused risk sharing models
3) Address barriers to risk sharing
4) Propose elements of model agreements
Pressure in the system driving change

Patient expectations
• Demand for timely access and emphasis on unmet need

Scientific challenge:
• Fragmentation of treatment populations
• Early disease interception
• Uncertainty around new science (e.g., biomarkers, etc.)

Healthcare systems and innovative companies are under pressure
• Affordability crisis
• Sustainability of drug development called into question by increasing requirements and spiraling costs

“The safest drug that no one can afford or that arrives too late is of no benefit to a patient.” (M. Skinner, Plenary HTAi Annual Conference 2014)
Objective of risk sharing agreements

Bridge the divide between perceptions of value
✓ Alleviate concerns about financial or clinical uncertainty
✓ Improve quality of care and patient access (for the right patients)
✓ Learn more about use in real-world setting
**HTA and Regulatory Early Scientific Advice**

<table>
<thead>
<tr>
<th>CHALLENGES</th>
<th>BENEFITS</th>
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<tbody>
<tr>
<td><strong>For all stakeholders</strong></td>
<td><strong>For all stakeholders</strong></td>
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<tr>
<td>• Jurisdictional and contextual differences</td>
<td>• Better awareness roles and remits</td>
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<tr>
<td>• Differences in remits and purposes</td>
<td>• Opportunity to build trust and understanding</td>
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<tr>
<td>• How to resolve conflict</td>
<td>• Efficiency gains</td>
</tr>
<tr>
<td><strong>For industry</strong></td>
<td><strong>For industry</strong></td>
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<tr>
<td>• Concerns about sharing proprietary information</td>
<td>• Facilitates drug development planning</td>
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<tr>
<td>• How to satisfy diverse requirements</td>
<td>• Greater understanding of differences in requirements</td>
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<tr>
<td>• Concerns about increasing evidentiary burden</td>
<td>• Coordination across multiple markets</td>
</tr>
<tr>
<td><strong>For regulatory / HTA / coverage bodies</strong></td>
<td><strong>For regulatory / HTA / coverage bodies</strong></td>
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<tr>
<td>• Resource demands</td>
<td>• Improved coordination of evidentiary expectations</td>
</tr>
<tr>
<td>• Legal constraints</td>
<td>• Opportunity to clarify why requirements may be different</td>
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<tr>
<td>• Working with different stakeholders</td>
<td>• Potential reduction of advice duplication</td>
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## Improving advice processes

### At the level of individual initiatives
- Feedback from all stakeholders
  - Advantage: timely and detailed
- Needs to be: transparent, publicly available
- Allows the individual process to evolve and improve

### Comparison between initiatives
- Allows identification of strengths and weaknesses
- Facilitates improvement (internal / external)
- Helps guide development of new processes
- HTAi Interest Sub Group
Adaptive Pathways: a novel approach

- Require change across **entire lifecycle** of the drug
- Require **all stakeholders to provide input** and make trade offs
- **Prospectively planned** and flexible (one size does not fit all)
- “…development programme is (re)structured to allow for early approval and coverage of a new compound for a limited population…based often on smaller initial clinical studies”¹
- **Iterative phases of evidence gathering** to reduce uncertainties
- Approved indications, coverage and therapeutic value **re-evaluated** as new efficacy, safety, effectiveness data is developed
- Treatment **populations can be broadened or restricted** based on the reevaluations.

A range of payer programs with varying levels of complexity and uncertainty can address the value disconnect with payers.

- **Discount**
  - Most basic pricing concept: 'Anything less than full price'
  - A cap on the volume of a drug that can be sold at a given price; volume sold past over the cap is discounted

- **Price-volume cap**
  - Lending providers drugs to bridge the gap between usage and reimbursement

- **Financial (credit risk)**
  - Creating education programs to help improve patient quality of life and lower payer costs without rebates

- **Compliance (adherence)**
  - Offering a refund or compensation if patients fail to adhere to drug regimen

- **Education programs**
  - Offering a refund if a drug does not meet negotiated target outcomes

- **Phase IV benchmark guarantee**
  - Current or future price negotiations are tied to ongoing clinical studies

- **Patient outcome guarantee**
  - Patient outcome guarantees without objective clinical outcomes are considered "marketing patient outcome guarantees"

- **Cost of failure sharing**
  - Paying for medical expenses resulting from drug failure or related adverse events

Source: Simon-Kucher & Partners – August 2016
Both financial and performance-based arrangements have their specific advantages and disadvantages.

### Financial arrangements

**Advantages**
- Reduce budget impact uncertainty
- Reduce average cost per patient
- Support list visible price for international referencing
- Do not require sophisticated infrastructure

**Disadvantages**
- Do not address concerns on product-specific performance issues
- Do not avoid risk of access restrictions
- Can reduce the potential for maximizing revenues/price

### Performance-based arrangements

**Advantages**
- Show manufacturer's trust in the product
- Solve uncertainty around efficacy results
- Help maximize access and revenue/price potential
- Protect visible price for international referencing

**Disadvantages**
- Low effect on budget impact uncertainty
- Limited support in reducing the average cost per patient
- Require a sophisticated infrastructure
- Risk of potential revenue loss if efficacy is not finally proven in real-life experience

Usually, financial arrangements are preferred over performance–based arrangements as first negotiation option, unless products are submitted with immature data or are supported by soft-endpoints / proxies, leaving uncertainty around real-life results.
Long-term goal to have more value-based approaches

Discounts and rebates
Price-volume

France Agreement connecting patient adherence to reimbursement

U.S. Agreement with private payer
Reimbursement based on patient success ranked on various measures

U.S. Agreement with private payer
Measures lead indicators for positive patient health outcomes
Performance determines rebate levels
## Barriers to success

### Policy Environment
(barriers to company engagement)

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<thead>
<tr>
<th>Unreasonable expectation of who owns the risk</th>
<th>Can fall heavily on manufacturer, payer, provider or patient</th>
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<tbody>
<tr>
<td>“Pile-on”</td>
<td>When multiple payer controls are layered on top of each other: HTA + budget impact assessment + reference pricing + MEA.</td>
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### Data and infrastructure
(barriers to all stakeholders)

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<tr>
<th>Procurement system challenges</th>
<th>Bids and tenders-based systems are not suitable for MEA as seeking a race to the bottom only</th>
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<tr>
<td>Administrative challenges</td>
<td>Costs and practicalities of administrating a complex agreement can be high</td>
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<tr>
<td>Poor data</td>
<td>Where access to data is limited, or quality is poor or if there is an inability to measure the results</td>
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Designing RSAs for success: Setting the policy framework

Voluntary

- Clearly defined measures
- Clearly defined timeline
- Clearly defined administration and governance
- Impact on access agreed

Confidential
Data must be sound and well managed

<table>
<thead>
<tr>
<th>Accessibility</th>
<th>Origin</th>
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<tr>
<td>Data Management</td>
<td></td>
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<tr>
<td>Site Management</td>
<td></td>
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<td>Reliable and credible</td>
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<table>
<thead>
<tr>
<th>Validity</th>
<th>Quality</th>
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<td>Generalizable and representative</td>
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<tr>
<th>Timely</th>
<th>Relevance</th>
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<td>Utility to specific objectives</td>
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<td>Sufficiency (complete, sample size)</td>
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Conclusion

• Bridge clinical and financial uncertainty
• Improve quality of care and patient access—for the right patients
• Provide real-world learnings
• Trending toward outcomes-based agreements
• The right policy framework and sound data generation and management can facilitate successful agreements
Challenge:
A company presents for HTA approval an oncology product (riccumab) that has a one month survival rate. The cancer type has typically poor survival (e.g., average 1 month from diagnosis). This introduces the concept of relative benefit (i.e., +one month is meaningful if a person has only one month to live, not so much if the person has 48 months).

The product also has a poorly defined tail (i.e., while the average is one month, a few will survive many months and maybe even a year). The point here is also 1) to show that decisions are not simple, 2) to show there are limitations of an average value, and 3) to help justify why a payer might consider one month as worth considering for reimbursement.

The HTA believes overall that this product falls short of the QALY and requests a risk sharing agreement.

How would the group design it? What would be their considerations for the RSA?