EFPIA has identified four key enablers of Innovative Payment Agreements(1)

Key Enablers

1 Concept
Gain endorsements from key stakeholders (especially academia and HTA) on the concept of MIP and combination pricing

2 Data Access
Demonstrate the ability to efficiently collect relevant data compliant with all data privacy and IT compliance regulations

3 Reimbursement mechanics
Advance the way that systems review prices and purchase medicines

4 Contracts
Design and implement contractual arrangements and implementation workflows (financial reconciliation)

Broad Stakeholder engagement underlying all efforts

(1) Enablers presented by Nathalie Moll at ECCO Summit September 2018
IQVIA’S Oncology Data Network

- Enabling care quality improvement
- Connecting the cancer community
- Describing current care and (inter)national variation

Life Science
- Up-to-date, continuous real world data
- Insight into actual product use
- Innovative payment agreement implementation

Healthcare
- 124 centers and growing
- 7 European countries
- 92,000 patients

Highly Automated
Near real-time
Direct comparability

Two main implementation questions

HOW?

How would we use the ODN, or other similar data sources, to implement innovative payment agreements?

For the purposes of agreement surveillance, what size network is needed to be representative of the national population?
Simulating innovative agreements using synthetic Real World Data (RWD)

**Methodology**

1. A synthetic RWD set was prepared based on the ODN dataset, cleaned, and used to model two agreements: Duration of Therapy (DoT) and Indication Based Payments (IBP).

2. National and sub-national surveillance cohorts (50%, 25%, 12% of total population) tested the variation in agreement outcomes.

3. 10 steps were identified to design, measure, forecast and reconcile agreements.

**Key Parameters**

- **Product modelled** – a large, multi-indication product based on synthetic ODN-like data (Simulacrum data)
- **Agreements modelled** – Duration of Therapy (DoT) and Indication Based Payments (IBP)
- **Surveillance cohorts** – 25% of patients was used as the base case, with additional analyses on 12% and 50% patient coverage
- **KPI Metric selected** – % of patients on therapy for less than 28 days
- **Total product usage** – breast, lung, prostate, and other was measured
- **Forecast of expected “curve”** (pre-agreement implementation) and proportion of patients with less than 28 days duration of therapy was determined to be 11.9% of patients
- **Agreement tracking monthly** – at month 12, % of patients less than 28 days was determined for reconciliation of agreement

We created three sub-national surveillance cohorts

Surveillance cohorts of 12%, 25% and 50% of total population were compared to the 100% “universe” population

analyses were executed for two agreement types for universe and cohorts.
To simulate the Duration of Therapy (DoT) agreement we set assumptions for expected RW product use, DoT, and agreement characteristics.

**Expected real world use of product under agreement**

- **< 28 days; 11.9% of patients**
- **No charge made**

**Agreement Characteristics:**
- Real world duration of therapy KPI for agreement
- If DoT < 28 days: no charge
- If DoT > 28 days: full payment

**Results: Duration of Therapy Agreement - Month 1**

- Median to date: 16
- Max observed duration of therapy in days: 31
- Total Number of patients to date: 203
- New patients initiated on treatment: 203
Results: Duration of Therapy Agreement - Month 2

Distribution of "Product" duration of therapy (25% of cohort), Month 2

- Median to date: 26 days
- Max observed duration of therapy in days: 61 days
- Total Number of patients to date: 391
- New patients initiated on treatment: 188

Results: Duration of Therapy Agreement - Month 3

Distribution of "Product" duration of therapy (25% of cohort), Month 3

- Median to date: 42 days
- Max observed duration of therapy in days: 92 days
- Total Number of patients to date: 559
- New patients initiated on treatment: 168
Results: Duration of Therapy Agreement - Month 4

Distribution of "Product" duration of therapy (25% of cohort), Month 4

- Median to date: 49 days
- Max observed duration of therapy in days: 123 days
- Total Number of patients to date: 737
- New patients initiated on treatment: 178

Results: Duration of Therapy Agreement - Month 5

Distribution of "Product" duration of therapy (25% of cohort), Month 5

- Median to date: 55 days
- Max observed duration of therapy in days: 151 days
- Total Number of patients to date: 918
- New patients initiated on treatment: 181
Results: Duration of Therapy Agreement - Month 6

Distribution of “Product” duration of therapy (25% of cohort), Month 6

- Median to date: 60
- Max observed duration of therapy in days: 182
- Total Number of patients to date: 1096
- New patients initiated on treatment: 178

Results: Duration of Therapy Agreement - Month 7

Distribution of “Product” duration of therapy (25% of cohort), Month 7

- Median to date: 67
- Max observed duration of therapy in days: 212
- Total Number of patients to date: 1249
- New patients initiated on treatment: 153
Results: Duration of Therapy Agreement - Month 8

Distribution of “Product” duration of therapy (25% of cohort), Month 8

<table>
<thead>
<tr>
<th>Median to date</th>
<th>77</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max observed duration of therapy in days</td>
<td>243</td>
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<tr>
<td>Total Number of patients to date</td>
<td>1424</td>
</tr>
<tr>
<td>New patients initiated on treatment</td>
<td>175</td>
</tr>
</tbody>
</table>

Results: Duration of Therapy Agreement - Month 9

Distribution of “Product” duration of therapy (25% of cohort), Month 9

<table>
<thead>
<tr>
<th>Median to date</th>
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</thead>
<tbody>
<tr>
<td>Max observed duration of therapy in days</td>
<td>273</td>
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<tr>
<td>Total Number of patients to date</td>
<td>1592</td>
</tr>
<tr>
<td>New patients initiated on treatment</td>
<td>168</td>
</tr>
</tbody>
</table>
Results: Duration of Therapy Agreement - Month 10

- **Distribution of “Product” duration of therapy (25% of cohort), Month 10**

  - Median to date: 83
  - Max observed duration of therapy in days: 304
  - Total Number of patients to date: 1765
  - New patients initiated on treatment: 173

Results: Duration of Therapy Agreement - Month 11

- **Distribution of “Product” duration of therapy (25% of cohort), Month 11**

  - Median to date: 87
  - Max observed duration of therapy in days: 335
  - Total Number of patients to date: 1905
  - New patients initiated on treatment: 140
Results: Duration of Therapy Agreement - Month 12

Distribution of "Product" duration of therapy (25% of cohort), Month 12

- Median to date: 92
- Max observed duration of therapy in days: 365
- Total Number of patients to date: 2064
- New patients initiated on treatment: 159

Patients <28 days:
- Total no. patients: 303
- % of patients: 14.7%
Minimal variation across cohort sizes was observed over a 2 year period, demonstrating that a representative cohort could be a pragmatic approach.

Metric: % of Patients with Duration of Therapy less than 28 days

<table>
<thead>
<tr>
<th>Tumour Type</th>
<th>N of Patients</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Jan 2017</td>
</tr>
<tr>
<td>Breast</td>
<td>183</td>
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<tr>
<td>Lung</td>
<td>5</td>
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<tr>
<td>Other</td>
<td>10</td>
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<tr>
<td>Prostate</td>
<td>5</td>
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</tbody>
</table>

This process revealed a repeatable 10 step approach

**Data Source and Metrics Selection**

**INPUT DECISIONS**

- Agreement Type
- Agreement Metrics
- Data Source
- Surveillance Cohorts
- Computation of KPIs
This process revealed a repeatable 10 step approach

INTEGRATION WITH AGREEMENT STRATEGY


This approach and the ODN provide a pragmatic solution to implementing innovative payment models

Agreement Design and Implementation

PharmaCo Agreement Design
- Agreement type and proposed conditions
- Expected real-world product performance
- Quantification of financial risk
- Price and payment setting

Value of Oncology Data Network Based Agreement for Payers
- Pay for value
- Minimal implementation burden of agreement
- Based on robust, observed real world product use
- Continuous monitoring of financial risk
- Timely reconciliation

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Abstract

A PROPOSED, SCALABLE APPROACH TO IMPLEMENTING INNOVATIVE PAYMENT AGREEMENTS

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OBJECTIVES: Interest in Innovative Payment Agreements (IPAs) that link product value or risk sharing to real-world practice e.g. by indication or Duration of Therapy (DoT) is increasing. Despite this and the existence of many real-world data (RWD) sources, no standard methodology for designing and implementing IPAs using RWD currently exists.

The European Oncology Data Network (ODN), established by the Collaboration for Oncology Data in Europe (CODE), led by IQVIA, is a collaborative near-real time RWD sharing platform designed to provide information on anti-cancer therapy usage and support the negotiation and implementation of IPAs.

In parallel to ODN development and in anticipation of its use supporting IPAs, this study aimed to describe a scalable approach to the design and implementation of IPAs using RWD.

METHODOLOGY: A simulated RWD set was prepared based on the ODN dataset, cleaned, and used to model two agreements: DoT and Indication Based Payments (IBP). Working with CODE members, nine steps were identified to design, measure, forecast and reconcile agreements. National and sub-national surveillance cohorts (50%, 25%, 12% of total population) tested the variation in agreements’ outcomes.

RESULTS: Complexities of using existing RWD sources not designed to support IPAs were revealed, including analytical choices (e.g. preparing and cleaning the data), evolving interpretation of the data (e.g. variations in DoT or indication over time) and requirements for measuring contextual variables (e.g. volume, new patients or indications) throughout the agreement. Variations based on surveillance cohort size, were quantified in the context of the risk associated with RWD measurement vs reliability of forecasting the future performance of the agreement.

CONCLUSION: This study highlighted the challenges inherent in using RWD for IPAs and proposed an approach to address them. It reinforced the need and benefit of using a ‘tailormade’ infrastructure with highly structured, near-real time data to develop and monitor IPAs.