Introduction

- Oncology medicines reimbursed in France have a fixed price whereas the benefits vary across patient groups.
- Pricing models aligned to the clinical benefit open an interesting concept, but they need to be supported by reliable and standardised metrics aligned with health authorities’ expectation.
- The Personalised Reimbursement Models (PRM) project is a global Roche project inspired by the Italian pricing system.
- In France, the PRM approach aims to establish an infrastructure to collect routinely existing data in order to be used as input for pricing models.
- A pilot phase has been achieved in 2014 to validate the feasibility of the of the project.

Objective

The aims of the pilot phase were:
- To validate the PRM infrastructure
- To evaluate the quality of data available in the Electronic Pharmacy Record

Methods

Pilot phase
- All metastatic breast cancer (mBC) patients at 14 pilot centres recorded in the Electronic Pharmacy Record (EPR) system with at least one trastuzumab claim between January 2011 to October 2014 that were not enrolled in a clinical trial were selected (Figure 1).
- Data related to demographics, disease description, drug usage and clinical outcomes were collected in the EPR (Figure 2). These data were controlled, cleaned and centralised in an anonymous and secure way through an accredited hosting provider.
- Patients were followed from the index date (first Trastuzumab claim) until six months after last date any drug prescription recorded in the EPR (Figure 1).

Scale-up phase
- The recruitment of around 100 additional centres began in January 2015
- A cluster sampling method by region and type of centres (university hospitals, general hospitals, anti-cancer centres and private clinics) has been used to ensure clinical practice representativeness.
- The retrospective longitudinal follow-up will be updated by routinely data extractions every 4 months.

Results

Proven data sharing process between healthcare centres and a third party:
- PRM infrastructure was built with a third party accredited by the Health Ministry to collect and analyse patient data.
- Data flow and patient data protection have been validated by the National Data Privacy Committee (CNIL).
- Several extractions have confirmed the infrastructure’s robustness.

Quality of data available in the Electronic Pharmacy Record:
- Data of 510 mBC patients taking trastuzumab were extracted through the pilot phase.
- 30 variables were identified as variables of interest to cover PRM objectives. Among them, 21 were available in the EPR with a 3.5% average of missing data. Results of these variables are presented in the Table 1 and compared to literature figures.

Table 1. comparison results of pilot phase vs literature data

<table>
<thead>
<tr>
<th>Variables available in the EPR</th>
<th>Pilot phase (n=510)</th>
<th>Literature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>61.8 years</td>
<td>61 years²</td>
</tr>
<tr>
<td>Weight</td>
<td>65.3 kg</td>
<td>64 kg²</td>
</tr>
<tr>
<td>Trastuzumab administered quantity</td>
<td>6.03 mg/kg/3 weeks</td>
<td>6 mg/kg/3 weeks²</td>
</tr>
<tr>
<td>Proportion of patient by line of treatment:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1st line</td>
<td>45%</td>
<td>40%²</td>
</tr>
<tr>
<td>2nd line</td>
<td>14%</td>
<td>26%²</td>
</tr>
<tr>
<td>3rd line</td>
<td>10%</td>
<td>33%²</td>
</tr>
<tr>
<td>Not available</td>
<td>3%</td>
<td></td>
</tr>
</tbody>
</table>

Conclusion

- Pilot study has validated technical and legal feasibility of the PRM infrastructure implementation and outputs quality.
- Over time, through this automatic data collection, PRM will deliver robust and standardised real world evidence that could be used to implement models that will support more flexible pricing strategies and help ensure patient access to innovative treatments delivered in different indications. This tool extends the number of agreements the French Authorities could discuss with pharmaceutical companies.

References

3. Internal modelling based on epidemiology data
4. SmPC (Summary of Product Characteristics) Herceptin® and Kadcyla®