Objective: To develop a new safety assessment framework for post-marketing drugs using medical information databases in Japan.

Methods: The following 5 steps were applied to develop the MIHARI project.
1. Preparation of databases
2. Signal Detection
3. Diagnosis Procedure
4. Electronic Medical Record (EMR) data
5. Data Mining

Results: In the fifth year, MIHARI was at the fifth and the fourth steps described in the methods. Some pilot studies about risk assessment and drug utilization using claims data were performed in this year. Based on the accumulated findings, knowledge, and experiences from the previous pilot studies in the last 5 years, we summarized features of each database available in Japan in order to make efficient use of those databases for the purpose of drug safety assessment. We have started using these databases as invaluable sources of information for pharmaco-vigilance.

Conclusion: We established a network to commence operations of the national safety assessment system for post-marketing drugs using Japanese medical databases. We have achieved the goal of MIHARI project successfully over this 5 years, and consequently we will apply this framework to management of drug safety in PMDA and make the system more advanced in the next mid-term (FY 2014-2018).

Pilot studies: We conducted more than 40 pilot studies in the past 5 years. In fifth year, we conducted the following pilot studies:
1. The assessment of the risk of acute asthma exacerbation associated with non-steroidal anti-inflammatory drugs using claims data from health insurance associations with the SCCS design. Some results from the study are shown in the poster presentation (poster no. 526).

2. Drug Use Study about Heparin or Amiodaron using DPC data. Some results from the study are shown in the poster presentation (poster no. 240).

Table 1. Summary of characteristics of databases used in MIHARI Project

<table>
<thead>
<tr>
<th>Data sources</th>
<th>Patients</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Claims data from health insurance associations</td>
<td>2005-2012 190M patients Inpatients &amp; out patients</td>
<td>All patients in the medical claim information are included unless the patient changes the health insurance association</td>
<td>Elderly people are not included. Only medical information covered by health insurance is available. Limit to follow-up (for example, before before April 2012)</td>
</tr>
<tr>
<td>Diagnosis Procedure</td>
<td>2011-2012 128 hospitals Inpatients only</td>
<td>Rich information about patient background (including BMI, smoker, etc.)</td>
<td>Frequent change of table format (uneasy to combine several years data) Only inpatient data covered by DPC system Lack of data from other hospitals Unable to follow-up for long term. Unable to link to the EMR data</td>
</tr>
<tr>
<td>Electronic Medical Record (EMR) data</td>
<td>2007-2011 6 hospitals Inpatients &amp; out patients</td>
<td>Include detailed medical information (ex. lab test data) Include insurance uncovered data</td>
<td>Small population Some contents need data cleaning Luck of data from other hospitals</td>
</tr>
</tbody>
</table>

Signal Detection: We proceeded with cooperation of the hospital staff in this study. We also appreciate useful suggestions from all members in PMDA Experts Committee on Use of Electronic Medical Information for Drug Safety.