Background: Objectives: REFLECT study has been carried out to assess in real life the use of CT-P13, the first monoclonal antibody biosimilar to infliximab (IFX) approved in France. Long-term real-life data on CT-P13 use are limited in patients (pts) suffering from rheumatic diseases and inflammatory bowel diseases.

Methods: REFLECT is a multicenter, prospective, observational study conducted in France which aims to describe characteristics of pts' receiving CT-P13 and to assess its safety and effectiveness in real-life conditions. Eligible pts for inclusion were pts (≥ 6 years old) with RA, axSpA, PsA, and inflammatory bowel disease treated with CT-P13. IFX naïve pts (IFX-N) or those having switched in the past 18 months from IFX originator to CT-P13 were enrolled (IFX-S). An intermediate result in pts of IFX originator to CT-P13 was effective in inducing and maintaining remission in both naïve and switched patients. This real-life study did not highlight any new safety concerns.

Conclusion: The results from this long-term follow-up period show that CT-P13 was effective in inducing and maintaining remission in both naïve and switched patients. This real-life study did not highlight any new safety concerns.

Disclosure of Interests: Hubert MAROTTE Grant/research support from: Bristol-Myers Squibb, Lilly France, MSD, Novartis, Nordic Pharma, Pfizer, Sanofi-Aventis, Consultant of: AbbVie, Amgen, Bristol Myers Squibb, Lilly France, MSD, Novartis, Nordic Pharma, Pfizer, Sanofi-Aventis, Paid instructor for: Sanofi-Aventis, Speakers bureau: Sanofi-Aventis, amel tamzali Employee of: Pfizer, Bruno Fautrel Grant/research support from: AbbVie, Lilly, MSD, Pfizer, Consultant of: AbbVie, Biogen, BMS, Boehringer Ingelheim, Celgene, Lilly, Ljanssen, Medac MSD France, Nordic Pharma, Novartis, Pfizer, Roche, Sanofi Aventis, SOBI and UCB

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Table 1. Reasons for treatment withdrawing

<table>
<thead>
<tr>
<th>Symptom listed on MDHAQ/MEDI60</th>
<th>DMRAD naïve (N=149)</th>
<th>DMRAD treated (N=379)</th>
<th>Methotrexate (N=153)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>28%</td>
<td>36%</td>
<td>36%</td>
</tr>
<tr>
<td>Unusual fatigue</td>
<td>31%</td>
<td>33%</td>
<td>34%</td>
</tr>
<tr>
<td>Anxiety</td>
<td>23%</td>
<td>27%</td>
<td></td>
</tr>
<tr>
<td>Cough</td>
<td>16%</td>
<td>18%</td>
<td></td>
</tr>
<tr>
<td>Dizziness</td>
<td>14%</td>
<td>18%</td>
<td>20%</td>
</tr>
<tr>
<td>Hair loss</td>
<td>10%</td>
<td>17%</td>
<td>19%</td>
</tr>
<tr>
<td>Nausea</td>
<td>11%</td>
<td>13%</td>
<td>18%</td>
</tr>
<tr>
<td>Skin rash or hives</td>
<td>11%</td>
<td>14%</td>
<td>13%</td>
</tr>
<tr>
<td>Stomach pain/cramps</td>
<td>9%</td>
<td>16%</td>
<td>15%</td>
</tr>
<tr>
<td>Eye problems</td>
<td>9%</td>
<td>13%</td>
<td>14%</td>
</tr>
<tr>
<td>Anorexia/weight loss</td>
<td>10%</td>
<td>16%</td>
<td>17%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>5%</td>
<td>9%</td>
<td>8%</td>
</tr>
<tr>
<td>Fever</td>
<td>5%</td>
<td>5%</td>
<td>7%</td>
</tr>
<tr>
<td>Mouth sores</td>
<td>3%</td>
<td>7%</td>
<td>8%</td>
</tr>
</tbody>
</table>

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stomach pain or cramps, eye problems, and/or weight loss; and 5-10% diarrhea, fever, and/or mouth sores (Table). Similar proportions were seen for Mtx-treated patients, although anxiety and cough were not listed as specific adverse events.

Conclusion: The MDHAQ symptom checklist may prove valuable to detect adverse events of high-risk medications, including on an electronic MDHAQ, which could be completed at home for 12 weeks after initiation of a new medication as a cost-effective approach for early detection of adverse events.

Disclosure of Interests: Kyle Schroeder: None declared, Sara Abu Mehsen: None declared, Isabel Castrejon: None declared, Theodore Pincus Shareholder of: Dr. Pincus holds a copyright and trademark on MDHAQ and RAPID3 for which he is the holder of:

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