Country | Estimated number of patients that can be included | Proposed number of patients allowed to be included
--- | --- | ---
Austria: | 50 | 50
Czech Republic: | 85 | 60
France: | 450 | 250
Germany: | 100 | 75
Great Britain | 125 | 90
Greece | 85 | 60
Italy: | 150 | 110
The Netherlands: | 65 | 50
Rumania: | 38 | 50
Spain: | 275 | 150
Sweden: | 75 | 55
Total | 1498 | 1000

<table>
<thead>
<tr>
<th>Estimated number</th>
<th>Proposed number</th>
<th>Proposed factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;50-50</td>
<td>50</td>
<td>na</td>
</tr>
<tr>
<td>50-150</td>
<td></td>
<td>0.71-0.75</td>
</tr>
<tr>
<td>&gt;150</td>
<td></td>
<td>0.55-0.56</td>
</tr>
</tbody>
</table>

Since the inclusion period is decreased from 18 months to 12 months the approach of inclusion should be changed.

Proposal:

During the inclusion year in total 1000 patients can be included in the EUMDS registry. The maximum number of patients that may be included per country is the number of patients that is mentioned in the contracts of the referral centers with the sponsor. When after 6 months of inclusion, it appears that inclusion of 750 patients after 8 months will not be feasible, than after 6 months the inclusion will be competitive. Afterwards the inclusion will depend on the agreement between the sponsor and Novartis.