

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

Estimated number	Proposed number	Proposed factor
<50-50	50	na
50-150		0.71-0.75
>150		0.55-0.56

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.