

IMACS FORM 11: ASSESSMENT OF STUDY OUTCOME

Subject's IMACS number _____

Assessor _____

Date of assessment (mm/dd/yy) _____

Assessment number _____

PHYSICIAN ASSESSMENT OF OUTCOME IN THE TRIAL/STUDY

Change in Disease Activity

Based upon all the information available to me at this time, I believe that compared to the condition of the subject on _____ (mm/dd/yy), the subject's disease **activity** is now (please check only one):

- Markedly improved
- Moderately improved
- Slightly improved
- Unchanged
- Slightly worse
- Moderately worse
- Markedly worse

According to the criteria for improvement used in your trial/study (primary endpoint), does this patient now meet the improvement criteria?

- Yes, this patient meets this trial's/study's improvement criteria at this time
- No, this patient does not meet this trial's/study's improvement criteria at this time
- This trial/study does not have improvement criteria

The improvement criteria for this trial/study are (primary endpoint criteria):

- IMACS Definition of Improvement (improvement in at least 3 of 6 core set measures by $\geq 20\%$, with no more than 2 worse by $\geq 25\%$, which cannot be MMT)
- Other: (specify) _____

IMACS has currently defined a complete clinical response as a 6-month continuous period of no disease activity while still receiving myositis therapy and clinical remission as a 6-month continuous period of no disease activity while not receiving any therapy for myositis. Based on this information please check all of the following that apply:

My patient currently has:

- Complete Clinical Response by IMACS criteria
- Complete Clinical Response by other criteria: Specify: _____
- Clinical Remission by IMACS criteria
- Clinical Remission by other criteria: Specify: _____
- None of the above (my patient's myositis remains active)
- Don't know

Change in Disease Damage

Based upon all the information available to me at this time, I believe that compared to the condition of the subject on _____ (mm/dd/yy), the subject's disease **damage** is now (please check only one):

- Markedly improved
- Moderately improved
- Slightly improved
- Unchanged
- Slightly worse
- Moderately worse
- Markedly worse

SUBJECT ASSESSMENT OF OUTCOME IN THE TRIAL/STUDY

Subject's IMACS number _____

Assessor _____

Date of assessment (mm/dd/yy) _____

Assessment number _____

Based upon everything that I know about me and how I feel at this time, I believe that compared to my condition on _____ (mm/dd/yy), I am now (please check only one):

- A great deal better
- Moderately better
- Slightly better
- No change
- Slightly worse
- Moderately worse
- A great deal worse

I believe that I have achieved:

- No evidence of myositis activity, but still taking myositis therapy
- No evidence of myositis activity and off all myositis therapy
- Neither: my myositis remains active
- Don't know

PARENT ASSESSMENT OF SUBJECT OUTCOME IN THE TRIAL/STUDY

Subject's IMACS number _____

Assessor _____

Assessor's relationship to subject: Mother:___; Father___; Other (specify):_____

Date of assessment (mm/dd/yy) _____

Assessment number _____

Based upon everything that I know about my child and how he/she feels at this time, I believe that compared to his/her condition on _____ (mm/dd/yy), they are now (please check only one):

- A great deal better
- Moderately better
- Slightly better
- No change
- Slightly worse
- Moderately worse
- A great deal worse

I believe that my child has achieved:

- No evidence of myositis activity, but still taking myositis therapy
- No evidence of myositis activity and off all myositis therapy
- Neither: my child's myositis remains active
- Don't know