



# Methotrexate and Prednisolone study in Erythema Nodosum Leprosum

## MaPs in ENL

Training session 15 – Study  
completion or termination

Dr. Barbara de Barros – MaPs study manager

# ENLIST



# Study Completion and Study Termination

- **What is the difference between completion and termination**
- **When**
- **Form to be completed**

# Study Completion

- The last visit – 19<sup>th</sup> visit
- Participant completes the follow up (60 weeks)
- Record if participant completed the full course of medication ( 52 weeks)
- Record if the participant received additional prednisolone
- Clarify any question
- Reinforce that the participant will continue to have medical assistance

# Study termination

- Participant can withdraw anytime during the study
- Lost of follow up
- Record the raison
- Assure the participant he/she will continue to receive medical treatment
- Clarify any question

# Study Completion or Termination form

- The form can be completed any visit.
- It can be completed in any visit

Screening ID 4

Completion or termination date:  Today D-M-Y

Did the patient complete the full course of medication?  Yes  No

Did the patient receive additional Prednisolone?  Yes  No

Did the patient report for all examinations after treatment?

	Yes	No
Week 48	<input type="radio"/>	<input type="radio"/>
Week 52	<input type="radio"/>	<input type="radio"/>
Week 56	<input type="radio"/>	<input type="radio"/>
Week 60	<input type="radio"/>	<input type="radio"/>

If the patient did not complete the medication or follow-up, select the reason:

- Subject did not return for clinic visit
- Protocol violation (specify)
- Subject refused study procedure(s)
- Voluntary withdrawal
- Illness (specify)
- Death (specify date)
- Severe side effects
- Other reason (specify)

Enter details of reason(s) for not completing follow-up

Additional Comments:

I have reviewed the contents of this case report form and found it to be complete and accurate. [Add signature](#)

Form Status

Complete?

Save & Exit Form Save & Stay -- Cancel --

Delete data for THIS FORM only

# Summary

- **Participants can withdraw from the study anytime**
- **Last visit 19<sup>th</sup> visit (the on the 60<sup>th</sup> week)**
- **Lost of follow up (after 2 missing visits)**
- **Always complete the form**
- **Clarify any question and reassure the participant that his/her leprosy treatment will not be affected**