

SUMMARY OF HOME III OUTCOMES

Signs domain – decisions made

- The core outcome measure for the signs domain should:
 - Include intensity *and* extent of the clinical signs
 - Be assessed by an investigator
 - Include erythema, excoriation, oedema / papulation and lichenification
- No other signs were considered essential to reflect the construct of the disease.
- Objective SCORAD and EASI include the four essential signs and perform adequately in validation studies.

MAIN OUTPUT FROM MEETING: Agreed by consensus that EASI will be recommended as the instrument outcome set for measuring the signs of eczema.

- The proposal to recommend that objective SCORAD be measured in addition to EASI in future clinical trials where possible was rejected.

Next steps:

- Publish the systematic review.
- Publish the consensus statement on EASI as the core outcome.
- Publicise the use of EASI as the core outcome.

Symptoms domain – decisions made

- The measurement of symptoms is messy – many different outcomes currently used.
- Need to ensure that the overlap with QoL is considered at all times.
- Agreed that the symptoms domain needs to cover more than just itch and sleep loss.

Next steps:

- Complete the project to identify which symptoms are important to patients.
- Follow the HOME roadmap starting with a systematic review of all measures of symptoms and validation.
- Validation of the POEM scales has been considered in the signs review and this could be used to inform the symptoms group.

Quality of Life domain – decisions made

- Generic scales can perform better than perhaps previously thought.
- Should look to new methodologies being used in this field such as PROMIS.
- Lots of work to be done in this domain.
- Extremely important to get patient input.

Next steps:

- Get the systematic review team in place.
- Agree the protocol for the systematic review.
- Conduct the systematic review.

Long Term Control domain – decisions made

- This domain presents an especially big challenge; neither repeated serial measurements of the other 3 domains or a measure of flares / WCW as ways of measuring long term control have much data to support their use.
- Flares or well controlled weeks (as currently defined) both have disadvantages which may make them unsuitable for the core outcome measure and it is not clear how they should be measured.
- Agreed by consensus that long term control should apply to trials of more than 3 months' duration.

Next steps:

- Before progress can be made in this domain, what is meant by long term control needs to be clarified through more in depth discussion.
- Systematic review to establish how long term control has been captured and any validation studies.