MAPPING CLINICAL TRIAL OUTCOME MEASURES FOR ATOPIC DERMATITIS

NICHOLAS NAUMOV
B.S. PHARMACOLOGY AND DRUG DEVELOPMENT
FACULTY MENTOR
EUNJOO PACIFICI, PHARMD, PHD
31.6 million people in the U.S. have some form of eczema.

One in 10 individuals will develop eczema during their lifetime.

AD disproportionately affects children and adolescents. AD also results in significant lifestyle and economic impacts.

Previous AD trials were using an array of different endpoints. It is not clear if trials are adhering to recent FDA guidances.

New FDA guidelines suggesting earlier inclusion of pediatric populations in AD studies was only published in 2018.
OUTCOME MEASURES

**Investigator’s Global Assessment (IGA)**
- Global assessment of the overall severity of the disease (1-5).

**Eczema Area and Severity Index (EASI-75)**
- Measures extent and severity of the disease.
  - 1. Redness, 2. Thickness, 3. Scratching, 4. Lichenification

**Pruritus Numeric Rating Scale (NRS)**
- Subjects rate itching intensity (1-10).
RESEARCH OBJECTIVE

To compare different AD trial outcome measures.
METHODODOLOGY

1. Compile a list of AD trials from clinicaltrials.gov
2. Examine published trial data.
3. Isolate data on outcome measures, treatment type, study type, and study phase.
4. Categorize outcome measures and stratify by type of product and trial phase.
5. Compare to published FDA guidance documents.
6. Assess data for trends.
### RESULTS – OUTCOME MEASURE ADHERENCE

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Outcome Measures</th>
<th>Biologic (n=16)</th>
<th>Immunosuppressive (n=14)</th>
<th>Other (n=20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IGA</td>
<td></td>
<td>56.25%</td>
<td>28.57%</td>
<td>45%</td>
</tr>
<tr>
<td>EASI-75</td>
<td></td>
<td>75%</td>
<td>35.71%</td>
<td>35%</td>
</tr>
<tr>
<td>NRS</td>
<td></td>
<td>37.5%</td>
<td>28.57%</td>
<td>25%</td>
</tr>
<tr>
<td>AVERAGE (n=50):</td>
<td></td>
<td><strong>56.25%</strong></td>
<td><strong>30.95%</strong></td>
<td><strong>35%</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Trial Phase</th>
<th>Outcome Measures</th>
<th>Phase I/II (n=32)</th>
<th>Phase III (n=8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IGA</td>
<td></td>
<td>46.87%</td>
<td>75%</td>
</tr>
<tr>
<td>EASI-75</td>
<td></td>
<td>50%</td>
<td>100%</td>
</tr>
<tr>
<td>NRS</td>
<td></td>
<td>34.37%</td>
<td>75%</td>
</tr>
<tr>
<td>AVERAGE (n=40):</td>
<td></td>
<td><strong>43.75%</strong></td>
<td><strong>83.33%</strong></td>
</tr>
</tbody>
</table>

Biologic medication trials comprised the largest single product type with the highest percentage adherence to suggested outcome measures.

There is a sharp increase in outcome measure adherence between Phase I/II and Phase III trials.
CONCLUSIONS

FDA guidance has not been fully implemented in AD trials. It would be informative to see if the adoption rate will increase over time.
FUTURE RESEARCH

What is the status of pediatric AD studies?

Is harmonization of trial endpoints possible?
REFERENCES


QUESTIONS?

NICHOLAS NAUMOV
NAUMOV@USC.EDU
PHARMACOLOGY AND DRUG DEVELOPMENT, B.S.