



European
Reference
Networks



RDEB Clinical Severity Score

Create an severity score for dystrophic EB **easy to use** in clinical practice and in clinical trials

ERN EB group meeting

24 February 2023

Complex existing scores
EBDASI
iscorEB

Delphi Method

Literature review :

on going bibliography studies / estimated delay : April 2023

Selection of experts

Development of the first questionnaire

estimated delay : Summer 2023

Questionnaire administration and analysis

Adaptation and analysis of successive questionnaires (3 runs)

estimated delay : Autumn-Winter 2023

Synthesis of the results and validation of the severity score

Physical meeting

estimated delay : End of 2023

Literature review: ongoing

2 independent reviewers

Pauline Bataille (Fellowship)

Ines Gannar (Resident)

Selection of Experts

C Has, C Bodemer

ERN Skin EB members

Researchers

Patients

Industry representatives

The experts who will be consulted throughout the DELPHI® method process.

The choice of experts must take into account their :

- Knowledge of the issue
- Legitimacy in relation to the group
- Availability throughout the DELPHI® method process.
- Independence from any form of pressure.

The final number of experts is not less than 25.

The recruitment of experts will be done through a network.

The experts will be contacted by e-mail, in order to :

- Explain the purpose of the project and how it will be carried out.
- Tell them what is expected of them and their investment.
- Solicit their participation.

Conducting the questionnaires

Three successive questionnaires will be offered to the experts, corresponding to the three rounds of the Delphi® method

These will be available on a dedicated platform via an invitation to respond by e-mail

Two reminders will be sent at 10 and 20 days, and if no response is received at 30 days, the experts will be automatically excluded

First questionnaire: guideline throughout the project: it will just be enriched, at each round, with the results and comments generated by the previous round

Second round of questionnaires: experts receive the results of the first round and have to give their opinion on the questionnaire again, now having the opinion of the group consulted. If their new answer deviates significantly from the average of the group, they must justify it.

Third round: experts will be informed of the results of the second round and the comments justifying the deviating opinions.

This last round will give the final answers: the median consensus opinions and the dispersion of opinions around this median, which can be interpreted with the help of the justifications and comments collected from the experts.

Literature review: ongoing

2 independent reviewers

Pauline Bataille

Ines

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Development of IT support

Vanesa Delique

Quote

13 250 euros

Data hosting

Project hosted on a server with "Health Data Hosting (HDS)" accreditation, which attests to ISO 27001 certification respecting all the confidentiality rules required for the management of personal health data.

Data anonymity

The project does not require a prior request to the Commission Nationale de l'Informatique et des Libertés (CNIL), nor to the Comité de Protection des Personnes (CPP), as the data collected will be anonymous.

Dedicated development

A dedicated platform will be developed to specifically meet the needs of the project by computerising the DELPHI® method:

- Questionnaires (integration).
- Comments.
- Results (export and analysis).

The development will be carried out under PHP DevShell 3.5 (LGPL 3 license), whose source code will be made available at the end of the project.

To Summarize

Practical EB score of severity

Christine Bodemer and Cristina Has

✓ Where We are

- Literature review: ongoing
- Recruitment of a specialized webmaster with validated quote
- Registration on PROSPERO web site (Literature review)
- Registration on COMET web site (Outcomes consortium)



✓ TO DO

-Enlarged List of experts



-Retroplanning meetings
qualitative analyses



-Runs
e-mail votes



-Final score



Rating scale between 1 and 9 is used with the following meanings:

- ≥ 7 critically important domains
- > 3 and < 7 important but not critical domains
- ≤ 3 not important domains for a core set in this disease group

Rating Scale								
1	2	3	4	5	6	7	8	9
not important domains for a core set in this disease group			important but not critical domains			critically important domains		

Table 4.4 DelphiManager modified for OMERACT Domain Rating scale