



## Information sheet: NOMINATE – call for participants in Patient/Parent Advisory Board

EFCNI recently joined the research project team of “**NOMINATE**” (“Novel Outcome Measures IN AuToimmune DiseaseE”). The project is supported by Janssen (the Pharmaceutical Companies of Johnson&Johnson). It aims to identify the most relevant outcomes in the management of Hemolytic Disease of the Fetus and Newborn (HDFN) and specifically, to understand the impact of this disease on **parents and newborns** and their life.

This is a call for parents and patient representatives that have lived experience of HDFN and who would be open to becoming a member of the **Patient/Parent Advisory Board for this research project** and share their personal experience with this disease during a **virtual Patient/Parent Advisory Board Meeting**.

### Background

In some rare cases, a pregnant woman’s immune system can produce antibodies that attack the red blood cells of their own unborn baby (fetus). This can result in diseases like HDFN. HDFN occurs when the baby’s red blood cells are not compatible with the mother’s and her immune system sees the baby’s red blood cells as foreign and produces antibodies against them. When these antibodies bind to the baby’s red blood cells, the cells break down leading to the potentially life-threatening condition of fetal anemia (bloodlessness of the baby).

### Project overview

The NOMINATE project seeks to identify new or existing research outcomes in the management of HDFN. **Knowledge building**, as well as aiming for a **consensus** between the perspective of affected patients/parents and healthcare professionals are the main goals.

Firstly, a **review of the literature** (analysis and evaluation of existing research, articles, books etc.) is performed to identify previously reported outcomes.

The second step will be to conduct two separate virtual meetings: a **Patient/Parent Advisory Board meeting** and a **Healthcare Professionals Advisory Board meeting**. In these meetings, outcomes identified in the literature review will be discussed and ranked in order of relevance or importance by the respective group and individual perspectives of affected patients/parents will be shared in the Patient/Parent Advisory Board meeting.



**During the Patient/Parent Advisory Board meeting, participants will be invited to share their personal experience with HDFN. Your feedback will be used to identify elements of most relevance for patients/parents.**

The third and last step of the project will be to **establish a consensus on the most relevant outcomes** that would optimally reflect the **impact** of the disease. This will be a joint effort where both patients and healthcare professionals will be able to share their perspectives and aim to reach an **agreement**. Patients/Parents who participated in the first Patient/Parent Advisory Board meeting are invited to contribute to this next step (taking place at a later timepoint), as well, if they would like to.

All of these insights will be further evaluated and characterized to ultimately publish a research paper explaining the importance of these outcomes in the management of disease. These insights will also be considered in future studies investigating HDFN.

#### **Who can participate in the Patient/Parent Advisory Board and what to expect?**

At this point, EFCNI is looking for parents or patient representatives from **Europe, older than 18 years, with a history of HDFN in a prior pregnancy**, who are willing to join the NOMINATE Patient/Parent Advisory Board and feel comfortable sharing their experiences with HDFN in **English**.

The goal of the Patient/Parent Advisory Board meeting is to discuss and evaluate “outcomes” that, in parents or patient representatives’ opinion, reflect the impact of the disease best. Active participation in the discussions, sharing honest opinions and perspectives on the outcomes described, as well as exchange of personal experiences will support the successful completion of the project.

Participation is completely **voluntary**. No further background knowledge is necessary. EFCNI will compensate the participants for their time investment and will support the Patient/Parent Advisory Board members with a briefing call before the meeting and a debriefing call shortly after the meeting.

Next to parents or patient representatives there will be attendees from EFCNI and Janssen present in the Advisory Board meeting.



### When and where will the Patient/Parent Advisory Board take place?

The Patient/Parent Advisory Board meeting is **virtual** and will proceed **once in October/November 2023**. The meeting will take up to 4 hours.

The follow-up meeting conducted together with healthcare professionals and patients/parents aiming to reach a consensus on the most relevant outcomes that reflect the impact of the disease from both perspectives will take place in 2024 for those who would be willing to join.

### What are the next steps if I am interested in participating?

If you are interested in participating, know someone who might be interested in participating or would like to request any additional information about the project or the specific tasks of the Patient/Parent Advisory Board, please do not hesitate to contact us by using the provided details below:

European Foundation for the Care of Newborn Infants (EFCNI)

Teresa Primavesi-Poggio: [Teresa.Primavesi-Poggio@efcni.org](mailto:Teresa.Primavesi-Poggio@efcni.org)

Thank you very much: Your participation in the NOMINATE project Patient/Parent Advisory Board will help to focus on results that matter most to parents and patients and will ensure that the perspective of patients and parents is considered - as a central component of this project and future endeavors.