ERN-BOND Questionnaire for patients on Diagnosis of Osteogenesis Imperfecta

INFORMATION SHEET AND CONSENT FORM

INFORMATION SHEET

The Objective of the Questionnaire

The aim of the ERN-BOND questionnaire is to provide a picture on the current situation in the 10 Member States (Belgium, Czech republic, Estonia, France, Germany, Italy, The Netherlands, Portugal, Sweden, United Kingdom) represented within ERN-BOND in regard to diagnosis and to identify the main challenges and potential solutions that could help reduce diagnosis delays. This activity will start from identifying existing care gaps within and among ERN-BOND full members and it will then collect patients information on their experience leading to the disease diagnosis. The results of the survey will feed into a White Paper that will shed light on the unmet needs of patients in this specific area and serve as a basis for a dialogue with policy-makers on the challenges related to diagnosis of rare bone diseases. The idea is to launch the questionnaire on diagnosis in the end of 2017 and extend it to other relevant topics in subsequent years.

The Focus

This questionnaire will focus on osteogenesis imperfecta (OI), one of the disease areas covered by ERN-BOND. Given the fact osteogenesis imperfecta represents a heterogeneous group of generic disorders that affect the bones, it will set an example for the replication of the questionnaire in other areas.

The Methodology

To conduct this work, ERN BOND Coordinator, the Rizzoli Institute of Bologna has published a tender and approached three agencies to develop a proposal for its implementation. Weber Shandwick, a Public Affairs Agency based in Brussels, was selected for conducting this work since their proposal met and exceeded all criteria that were specified in the brief. To gather input from both Healthcare Professionals and Patient Organisations, two questionnaires have been developed and carried out in October-November 2017. An ERN-BOND account will be created ad hoc for this task. To ensure anonymity and confidential use of patient-reported data, no personal information will be requested in the questionnaire. However, you will be asked to fill in a consent form prior to the completion of the questionnaire. Data will be analysed to identify the key challenges in diagnosis and compare access to diagnosis between and within the Member States represented within ERN-BOND. ERN-BOND Steering Committee and European Patient Advocacy Groups have been systematically consulted for the validation of the questionnaires and they will also be consulted for the analysis of findings and final report. The questionnaires have been developed in English but there will be the option for recipients to respond to questions in their native language. Access to the completed questionnaires will be only granted to the Agency.

The Sample Size

The questionnaires for healthcare professionals (HCPs) have been circulated for completion to the Bone Specialists of all ERN-BOND Members. For the dissemination of the questionnaires tailored to patients, each participating interviewee has been asked to identify 3 patients affected by any type of osteogenesis imperfecta and who are at differing time periods from diagnosis (e.g. recent diagnosis – patients who have been diagnosed less than 6 months ago; mid-term diagnosis – patients who have been diagnosed between 6 months and 2 years ago; and long term diagnosis – patients who have been diagnosed more than 2 years ago).

We expect to reach the following number of respondents:

- **The questionnaire for healthcare professionals**
  - Target number of respondents (bone specialists): 30
- **The questionnaire for patients**
  - Target number of respondents (patients and/or carers): 60

Timeline

- The questionnaire for healthcare professionals was circulated on 6 November to ERN-BOND full members with a deadline set on 3 November to complete the questionnaire.
- Each healthcare professional has been asked to identify 3 patients and explore their interest in participating in the survey. Healthcare professionals who have agreed to identify patients for the purpose of the survey have committed to duly inform them that their names and contact details have been shared with the ERN-BOND Project Manager and that a consent form would need to be completed and returned prior to the patient questionnaire.
- Each healthcare professional have sent the contact details of patients who agree to participate in the survey to ERN-BOND project manager, Matias de la Calle at matiasignacio.delacalle@ior.it
- The patients who are willing to take part in the survey will be asked to complete the following consent form prior to receiving the patient questionnaire with a deadline on 16 November.

What your participation in the questionnaire entails

Participation in this questionnaire required the sharing of personal information about your/your child's disease. If you accept to participate in this questionnaire, you will be asked to fill in a declaration of consent and a consent form.
You will not be charged for any of the activities related to the questionnaire and you will not be required to undertake any additional medical examinations for participating in this questionnaire.

Why participating in this questionnaire

We aim to collect information on diagnosis of osteogenesis imperfecta to call for policies that can reduce diagnosis delay in the future.

Which are the risks associated to your participation in this questionnaire

There are no risk associated to your participation in this questionnaire, which only aims to collect data related to the diagnosis of osteogenesis imperfecta.

What happens if you decide not to participate in this questionnaire

Your participation is voluntary and you are free to decide not to participate in this questionnaire. You can also decide to withdraw your participation at any moment.

Information on the results of this questionnaire

If you wish, we will share with you the finding of this questionnaire and the ERN-BOND White Paper

Additional information

For additional information, feel free to reach out to

- Matias de la Calle: matiasignacio.delacalle@ior.it
- Dott. Luca Sangiorgi: luca.sangiorgi@ior.it

You can report any facts you might consider inappropriate to the Ethical Committee of the Rizzoli Institute (Comitato Etico IOR: Segreteria Comitato Etico IOR, via Pupilli, 1 – 40136 Bologna, tel. 051 6366480, fax 051 6366291).

This protocol has been developed in compliance with the Good Clinical Practice of the European Union and with the current revision of the Helsinki Declaration and it has been approved by the Ethical committee of the Istituto Ortopedico Rizzoli.

Confidentiality of personal data

The personal data collected in the framework of the ERN-BOND questionnaire will be used only to the purpose of this study and will anonymously feed into a White Paper.
Your personal data will be treated by Istituto Ortopedico Rizzoli, situated in via Pupilli 1, 40136 Bologna, Italy.
The privacy policy of the Istituto Ortopedico Rizzoli is available here: http://www.ior.it/curarsi-al-rizzoli/i-diritti-del-paziente

Completed questionnaires will only be accessed by the Agency (Weber Shandwick), as "data processor", and treated confidentially and anonymously. The questionnaire is also subject to SurveyMonkey's Terms of Use, including its Privacy Policy. The data collected will be solely used for the purpose of the study and will not be used or sold for any other purposes, in compliance with Regulation (EU) 2016/679 and Directive (EU) 2016/680 of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data, and with any other applicable data protection legislation.

DECLARATION OF CONSENT

I, the undersigned:

Name :	Surname:
Country:	

confirm that I have read and understood the information sheet on the ERN-BOND questionnaire. I am also aware that if I have any concerns on the questions included in this questionnaire, or with regard to the processing of my personal data in this context, I can contact Matias de la Calle at matiasignacio.delacalle@ior.it

☐ I agree ☐ I do not agree

I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without this affecting my medical care.

☐ I agree ☐ I do not agree

I understand that relevant sections of the ERN-BOND questionnaire and data collected during the study, may be looked at by individuals from the agency (Weber Shandwick). I give permission for these individuals to have access to my records.

☐ I agree ☐ I do not agree

I agree to fill in the ERN-BOND questionnaire and I am aware that the data collected via the ERN-BOND questionnaire will feed into a White Paper and they will be available anonymously (DLgs. 196 del 30/6/2003).

☐ I agree ☐ I do not agree

Should further information on my answers be required, I provide my consent to be contacted by the ERN-BOND project manager Matias de la Calle for any concerns about the ERN-BOND questionnaire.

☐ I agree ☐ I do not agree

_________________ ____

Date Signature

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For carers (parents/relatives) in case the patient is not able to give its consent

I, the undersigned,

Name :	Surname:
Country:	

as carer (parent/relative) declare that

Name :	Surname:
Country:	

have correctly received all relevant information on the ERN-BOND questionnaire which is included in the information sheet. I also confirm my willingness to fill in the ERN-BOND questionnaire

_____ _____

Data Signature of the witness

CONSENT FORM

I, the undersigned:

Name :	Surname:
Country:	

Declare I have read the policy on personal data, I have understood and am aware of my rights stated in art. 7, D.Lgs. 30/06/2003, n 196 (so called Privacy Code);

In accordance with the article 23 of the Privacy Code, as well as the data protection law on the use of personal data[1]

☐ I agree ☐ I do not agree

to use my personal data for the purpose of the ERN-BOND questionnaire (as stated in the information sheet) and

☐ I agree ☐ I do not agree

to transfer my personal data to third parties (such as laboratories, hospitals and university hospitals, agencies) which can have a different level of protection of personal data.

_____ _____ _____

Place Date Signature

[1] Autorizzazione del Garante per la protezione dei dati personali n. 2/2016 del 15/12/2016 al trattamento dei dati idonei a rivelare lo stato di salute e la vita sessuale e Autorizzazione dello stesso Garante nr. 9/2016 del 15/12/2016 al trattamento dei dati personali effettuato per scopi di ricerca scientifica e Linee guida per i trattamenti di dati personali nell'ambito delle sperimentazioni cliniche di medicinali" del 24 luglio 2008