



**OSTEOGENESIS IMPERFECTA
FEDERATION EUROPE**

**Meeting report- AGM 27
Saturday 15th June – Sunday 16th June 2019**

Tallink Hotel, Riga, Latvia

List of participants

There were in total 34 participants to OIFE AGM 2019 excl. assistants and dinner guests

Participants from ordinary members with voting rights:

1. Ingunn Westerheim (IW), OIFE president & delegate Norway
2. Céu M. Barreiros (CB), OIFE Treasurer & delegate Portugal
3. Dace Liepina (DL), OIFE Vice president & delegate Latvia
4. Ida Männistö (ID), OIFE Vice president and delegate Finland
5. Ute Wallentin (UW), Social Network Coordinator & delegate Germany
6. André Wittwer (AW), OIFE Webmaster & delegate Switzerland
7. Michał Daszkowski (MD), delegate Poland
8. Coreen Kelday (CK), delegate UK & Ireland
9. Elena Meshcheryakova (EM), delegate Russia
10. Jean Moitry (JM), delegate France
11. Simona Paveri (SP), delegate Italy
12. Lyubov Petrova (LP), delegate Ukraine
13. Bruno Van Dijck (BvD), delegate Belgium
14. Taco van Welzenis (TvW), delegate Netherlands
15. Maria Barbero (MB), delegate Spain + Padrinos and AHUCE Foundation

Other participants from ordinary members (no extra vote):

1. Kristiana Berzina (KB), delegate Latvia
2. Julien Delaye (JD), OIFE Volunteer
3. Patricia Firminho (PF), delegate Portugal
4. Anna Rossi (AR), Communication Manager OIFE
5. Fatima Godinho (FG), OIFE MAB and delegate Portugal
6. Edward Liepins (EL), delegate Latvia
7. Leonardo Panzeri (LP) delegate Italy
8. Joshua Mattia Paveri (JM) Italy
9. Inger-Margrethe Stavdal Paulsen (IP), Norway
10. Aleksandra Romanycheva (AR), delegate Russia
11. Gabriel Zubowski (GZ), Poland

Participants from associate members (no vote):

1. Dagmar Mekking (DM), Netherlands, OIFE delegate (Care4BrittleBones)
2. Louise Adeleke (LA), OI Foundation Nigeria
3. Tarela Aghanti (TA), OI Foundation Nigeria

Invited guests for OIFE AGM (no vote):

1. Dominic Bowers (DB), UK Mereo BioPharma
2. Eva Åström (EA) - Member OIFE's Medical Advisory Board
3. Wills Hughes-Wilson (WHW), UK Mereo BioPharma
4. George Reynolds (GR) Ireland, RareUrn
5. Lidiia Zhytnik (LZ) Member OIFE's Medical Advisory Board

SATURDAY 15th June

OIFE Annual General Meeting (AGM) - business meeting

- Welcome and apologies
- Election of meeting volunteers
- Settlement of agenda
- Approval of minutes from 2018
- Approval of OIFE's Annual Report 2018
- Approval of financial report 2018
- Short status from Social Network Coordinator

Welcome and apologies

were given by IW. Apologies from Spain, Romania, Denmark and Austria.

Election of meeting volunteers

- Minutes: Julien Delaye and Coreen Kelday
- To-Do-List: Maria Barbero
- Counting of votes: Jean Moitry and IP
- Financial sub committee 2019: André Wittwer and Filip de Gruytere

Settlement of agenda

Vote: the Agenda is accepted unanimously.

Approval of minutes from AGM 2018

The minutes from AGM 2018 have previously been approved by email vote.

Approval of OIFE's Annual Report 2018

The Annual Report 2018 had been sent in advance. IW thanked all elected volunteers and all others who have helped throughout the year. She gave a brief overview of annual report given by IW. The full report can be read online: <https://oife.org/what-we-do/annual-reports>

Main points:

- 25th Anniversary celebrated in Dundee
- OIFE became more visible as international OI umbrella organisation
- 3 new member organisations: Ukraine, South Africa and Nigeria
- Increased collaboration and contact between organisations
- Google for Non-profits being used by EC to access documents & run the daily business
- New website launched in 2018, and increased use of other social media platforms
- Newsletter review was carried out (now called Magazine) and positive feedback received
- Lots of meetings with delegates and volunteers, first draft of financial policy developed, tasks to protect privacy data done/GDPR
- Increased relationships with Pharma companies
- Continuing to develop relationships with other rare bone groups

Challenges:

- EC priorities and clearer goals
- Funding is hard to predict

- Finding patient representatives with enough knowledge and availability/time
- Reaching target groups via email – i.e. firewalls in hospitals
- Culture for sharing ideas and practices

Conclusion:

- 2018 was a good year with several goals reached
- Medical Advisory Board established
- OIFE represented at various meetings globally
- New webpage and magazine both received good feedback
- EC are working well together
- Activity as a whole has been high and is getting higher - this is hard when all the work is being done by volunteers
- Goal for the future to have a paid staff member

IW asked for any comments and votes for approval of annual report. No comments given. UW congratulated IW and thanked her for how well things have gone.

Vote:

EC Report 2018 is unanimously approved without objections.

Approval of financial report 2018.

CB stated that accounts had been sent out by email prior to meeting and no questions had been received.

Overview of accounts:

- OIFE has opened a 2nd bank account due to legacy being left with stipulation (from Honorary President Rob van Welzenis). It was to be put into separate account and used only in an emergency.
- During 2018 a digital file for accounts was created - this means the finance subcommittee can review and audit the accounts in advance of the meeting.
- AW confirmed the accounts have been checked by 2 people and approved with no areas of concern.
- BvD gave approval on behalf of Filip de Gruytere from Belgium on finance sub committee
- TvW asked if everyone had had a chance to review accounts prior to meeting. He encouraged the EC to distribute the papers earlier.

Vote:

There were 14 approvals for accounts and 1 abstention.

Budget 2020

CB gave an overview of the proposed budget:

Specific Projects:

- Flying OI Experts
- Youth meeting
- Communication development
- Stronger bond between us
- OI2020
- OIFE Passport

SP asked about Flying OI experts budget and if there was anything specific planned for 2019. The 2018 funding was used for conference in Ecuador, South America and supporting travel costs for consultants and lecture in China. In addition dr. Forlino's attendance at the OIF Investigator meeting was supported. No confirmed plans yet for 2019/20. IW gave update on Stronger Bond between us Project.

Vote:

The budget is unanimously approved.

Membership applications

One application from OIF Ghana. EC had reviewed their application and sent out in advance to all OIFE member organisations for approval. Votes came back with a tight majority but too many abstentions to be able to confirm acceptance. The EC requested a formal vote at the meeting with all present.

Vote:

OIF Ghana is unanimously accepted as an associate member organization of OIFE.

Executive Committee – elections

Position of President and second vice president both up for election. IW and IM both happy to re-stand for another period of 4 years.

Vote for President: no other candidates. IW unanimously re-elected

Vote for Vice-President: no other candidates. IM unanimously re-elected.

News from ERN BOND

Presented by Eva Åstrøm

ERN Bond is one of the 24 approved European Networks. They are co-funded by the European Union.

Purpose of ERN

- To join the best specialists from across Europe to tackle complex or rare medical conditions that require highly specialised healthcare
- Main ambition to facilitate multidisciplinary patient centred care
- Goals for next 3 years are to encourage consolidation of the network, encourage communication, promote knowledge and patient participation.
- Currently 38 centres in 10 countries and 9 different working groups
- BOND members collaborate with Orphanet for classification of rare bone disease.
- Whitepaper presented in Brussels in relation to diagnosis & treatment from WG1.
- Overview given of each working group and what they are each working on, including WG4 and C4C Study and WG9 and implementation of Twitter, Facebook and LinkedIn pages for ERN BOND.

A couple of questions raised in relation to Brexit and when can new countries apply. It was noted that each working group has a team leader and an assistant team lead - only one of which can be an individual from the UK. IW showed the OIFE website and where to find more information about the ERNs. EC promised to check the deadlines for new applications and spread information to delegates.

Future events

- Youth Event 2020: From Aug 28th to 31st in Gdansk, Poland
- Youth Event 2021 possibly in Belgium
- III Latin-American OI Congress (MB) to be held in Quito, Ecuador 15th Oct 2019 in conjunction with Shiners Montreal. This will be a teaching conference. OIFE to send a Physiotherapist. Discussions to be held at the conference in relation to setting up a South American Organisation. A separate conference will be held for families during the same weekend.
- OIFE AGM 2020: IW stated it will not be held in Sheffield as it would be too much to have this in conjunction with another big event. Therefore planned to be held in Valencia, Spain from May 15th to 17th 2020.
- OI2020: Sheffield, 5^h to 8th Sep 2020. IW gave update: This is the biggest scientific OI conference held globally. Possibly to start with a one day seminar in relation to patient involvement in research.
- Quality of Life 4 OI: 22nd to 25th Nov 2019 - DM introduced the conference. Requested OIFE delegates to assist with promoting the conference to their healthcare professionals, and to think about how they may be interested in attending. Multi-Disciplinary Teams will be attending from all over the world. IM said a final word about the amount of work and confirmed how useful the workshops would be. DM gave an overview of the programme.

Status on the Asteroid Trial

presented by Dominic Bowers and Wills Hughs-Wilson, both from Mereo Biopharma

Brief introduction given about Mereo. They are a new company only 4 years old. 6 different programmes in development with one for OI. DB gave an overview of Setrusumab. Mereo hope this will be first approved drug specific to OI. Aim is to build new bone to help with overall management of the condition. Promising results have been shown from the phase 2B study of which 112 adult patients are enrolled. Study primarily is measuring the trabecular volumetric BMD by using a HRpQCT machine. To move the drug forward they need to start doing a Pediatric phase 3 study. Looking at recruiting 160 patients mainly within Europe and USA. Will be mainly a Fracture study – hope is to reduce fractures by 30%.

An overview of the analysis of the 6 month open label data was given. So far results are promising.

Overall objective is that the drug will be useful to patients and therefore it needs to be available to them.

Questions will need to be answered to the EMA. Quality, safety, efficacy, effectiveness, cost effectiveness will need to be reviewed and each country have different requirements they will look for. Mereo want to prepare upfront for this by developing an OI registry.

List of all stakeholders to be considered:

- Patients
- Physicians
- Regulators
- HTAs
- Pricing and reimbursement authorities and payers
- Investors

OI-registries today & tomorrow

Presented by George Reynolds, consultant for Mereo Biopharma

Why a registry is needed?

- to understand natural history
- to aid in negotiation with health authorities
- to build an evidence base
- to increase patient access
- to ensure best practice

All registries are not the same. – a basic population registry with diagnosis and demographics does not show progress for example. For drug approval purposes the registry needs to have a longitude overview. I.e. needs to be populated regularly – for example with annual patient assessment information.

Most patient organizations have registries but these are not official.

OIF in the US do have a registry:

- They want to collaborate in an international registry
- Longitudinal study of OI is very good platform
- Recommended that there should be two separate hosted sites that can share anonymised data (US/EU)

Clinical data collection challenges:

- Patient organizations have limited time and resources
- Responsibilities would be shared but suggested that the Patient Organisations would remain the detainers of registries.

First phase is to create national model registries that all countries can use. Then Local extensions, all of which could be coupled with a European federated registry. Lots of discussion and questions raised. Session continued on Sunday.

Sunday 16th June

OIFE today & tomorrow - where are we?

Where is OIFE today? – IW gave update. Summed up by saying its complicated as there is so much going on.

Research – Mereo clinical trial – IW explained the steps to get the drug approved – ie EMA then each country. Two members of the EC has attended the **EURORDIS summer school**, but there is still a need for more people to understand the process of getting drugs licensed for approval. The EC had invited Mereo to start the discussion in relations to registries so everybody was informed. OIFE need to learn from other rare disease groups.

OIFE are a member of EURORDIS and OI is one of the larger of the rare diseases. EURORDIS want to use OI as examples for some projects. For instance new project for repurposing of drugs i.e. alendronate for use in OI. OIFE has not accepted their offer until now.

National reports – AR gave an overview of all OIFE member organisations, this included:

- board size numbers and highlighted that most don't have paid staff.
- Relevant and new projects from some countries were mentioned.
- Social media mix used – facebook and website being top.
- OIFE activities – topical meetings and updates being top. Most delegates report OIFE news to their national boards. Challenges being lack of resources and funding.
- Centres of expertise – most countries have at least one centre.
- Registries out of 18 countries 7 reported they had some kind of a register.

IW requested everyone to find out what is happening in their country with registries. Some other stats discussed. Membership engagement discussion held.

Continued discussion from Mereo

DB gave an overview of the study and why the evidence from registries will be needed. WH explained this is not something Mereo would choose to do, but they are required to do this by the regulators.

WH stated that a marketing authorization from the EMA is not the end of the process. WH explained that for the EMA to give permission to put the drug on the market they will ask for follow up measures and this will probably be every six months for 5 years. Once the EMA give approval then Mereo need to go to each country and they will ask different questions and have different stipulations.

Why can't the Registry be done through the ERNs?

– GR explained that they can't because:

- the ERNs are not a legal entity
- each hospital in the ERN would have to have the consent
- also ERNs are looking at lots of conditions not just OI
- in addition ERNS don't want to be seen to have any bias
- neither are they allowed to receive grants from companies.

Key questions for OIFE from Mereo:

- Would the OIFE be interested to continue to be informed about the feedback that Mereo is receiving from the different European and National authorities about potential registry and continue the discussions?
- What areas of the proposal outlined are of particular interest or concern for OIFE and how can we address them with the authorities?

Research & development – various updates provided from different countries

Patient involvement in NFOI (adult clinics, rehab course, multidiscipl. clinic, ERN BOND-application) IM National Resource centre include an advisory board with patient reps - this includes involvement in strategic planning and involvement in developing an adult clinic. Patient involvement is mandatory in any Research carried out by Oslo University Hospital. There is a new rehabilitation course for adults with OI now established. NFOI have also recently provided a support letter for a registry to be funded and NFOI are pushing for an application to ERN.

BOOSTB4 (Boost Brittle Bone before Birth): Eva Åström gave an overview of study on stem cells - currently running in Sweden in UK and hopefully to be in the Netherlands and Germany. Looking at safety and efficacy. 15 patients on trial.

BBS policy activities (development of clinical care guidelines, NICE guidelines, campaigning for adult services) BBS - Patient priorities in research. CK gave an update on where the Brittle Bone Society are in relation to their campaign for adult services and discussions they have had with Policy makers. What they are doing to develop Clinical Care Guidelines and the importance of being involved in NICE consultations.

BBS Research Workshop – CK gave an update on the Research workshop held at the conference in Dundee in 2018 in which OIFE delegates also took part. The full report can be read [here](#)
CK also gave an update on the James Lind priority setting research consultation. The full report can be read [here](#). Both research papers are consistent with each other and top priorities for patient research is Pain, Fatigue, Sleep, Quality of Life.

News from Ahuce Foundation - (MB)

In Spain the research charity is a separate charity to the patient organisation, but run by the same board.

Various Projects:

- Psychological care – clinical sessions by skype to individuals
- Social and formative projects – HP computer company have funded loan equipment (ie wheelchairs)
- Workshops for living skills (how to present yourself for getting a job). Includes a social worker who goes to companies to promote the benefits of having someone with a disability. 6 people so far have jobs through the project
- Various research studies ongoing: Chronic Pain - to be presented in Amsterdam. Reference values in OI. Database of samples from bone study and characteristics. Bioengineering for OI. Rare Commons have 5000 euros to do a registry but now not answering any emails. Also dental, respiratory, genetic

Key4OI: DM informed us that Care4Brittle Bones was set up as a temporary organisation and will probably be obsolete in next 5 to 10 years. Key4OI consensus on most important topic for people in OI. Minimum set of data for health related QOL what is the minimum we agree on. 9 months of work and there will be a final 10 topics. Applied for a grant of 200.000 towards project still waiting to hear on success.

Other related activity: LZ update on what's happening in research in Europe. Clinical Trials from 2017 to 2019 many covered on OIFE website. Mereo and Amgen ongoing but also Bone Therapeutics (Belgium) and Genzyme Corp. Also gave overview of published articles collected from <https://www.clinicaltrialsregister.eu> . Slides to be sent out after meeting.

Sharing is caring – various updates given from different countries

OIFE's Social Network - challenges & possibilities UW provided update – Different ways people contact OIFE. Through facebook, website, emails other organisations. Sometimes people send to various contacts – i.e. OIF, OIFE, BBS etc so makes sense to centralise these so not all answering. Many queries are asking for visas but no matter what the query is about - just making contact sometimes leads to organisations being set up. Estimate 2 to 3 requests per week.

Some observations – social networking important, sharing ideas. Important to do but moderate by one person.

Projects & activities from the Netherlands – TvW updated all on project psychosocial aspects of OI in collaboration with Care4BB, this has led to running workshops. Symposium bisphosphonates, swimming with members. VOI have decided not to continue with their magazine. Only have an online mag. Pretty active at the moment, and important to have a variety of activities.

Online educational programme & camps Russia - AR provided update: Showed a slide on what they cover. Have 2 government grants. Online platform use ZOOM for webinar – discussed with children for social skills and course for success in total grants were 30000 and 75000 for 62 and 74 children participated. Other projects: optimistic stickers for wheelchair wheels, sharing wheelchair project and try different chairs (i.e. electric powered) to try and raise money for fund. Showed a film from their summer camp.

Bone Academy Portugal - CB provided an overview of aim of Charity and their goals. New project in Portugal - they now have a building for the first time since they started in 2006. Space to meet, looking at employing someone. Work ongoing to make the office accessible. They have started running educational sessions and developing brochures and digital booklet.

Ukraine activities to improve treatment + conference improve knowledge - LP provided update Started Society in 2015. Difficult to get treatment as OI drugs not approved for use in children. Patient group spoke with health minister and received support from OIFE and OIF and now improved treatments and a centre seeing OI patients. Now have booklets and flyers on OI.

A stronger BOND between us - the European Rare Bone Network - Presentation by Ingunn W. Inês Alves (Patient Rep in BOND) – leader of Achondroplasia Society in Portugal. Inês, IW and Gerald Brandt (HPP) to meet at ICCBH and do a networking event. Connected to OIFE idea stronger bond between us – OIFE want more members to represent at various meetings also financial reasons as opens opportunities for funding. Inês' agenda might be slightly different – she also wants to link up groups working with short stature throughout Europe. Also ECTS (member organisation for bone researchers) want to attract rare bone stakeholders. ECTS held a meeting in Valencia last year, where they tried to establish a rare bone network. There was a rep from OIFE there but no agreement to establish a network decided. After that an email came out saying there was a network agreed including Pharma companies. This was different to the minutes.

IW wants agreement from the board that OIFE should not be part of another umbrella organisation, if this is what the initiative develops into. But happy to collaborate & work together. Also finding there are too many emails connected to this project.

The patients voice in R&D - how do we find it?

No one person can say what do people with OI want. Various topics at conference with a patient rep involved in each topic to decide on what patients want answered. Question raised in relation to how this is different to James Lind Alliance.

Date: June 16th 2019

Place: Tallink Hotel, Riga, Latvia

Minutes taken by: Coreen Kelday and Julien Delaye