ESPGHAN Paediatric IBD Porto Group and the Open IBD Interest Group

Annual Report

Date of Submission: 14.7.19

1. COMMITTEE MEMBERS AND MANDATES

Administration

<table>
<thead>
<tr>
<th>Name</th>
<th>Positions held within Committee</th>
<th>Email address</th>
<th>Date of entry to the Porto group</th>
<th>1st Term</th>
<th>2nd Term</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dan Turner</td>
<td>Chair</td>
<td><a href="mailto:turnerd@szmc.org.il">turnerd@szmc.org.il</a></td>
<td>2011</td>
<td>2014-2017</td>
<td>2018-2020</td>
</tr>
<tr>
<td>Eytan Wine</td>
<td>Liaison for budget and research</td>
<td><a href="mailto:wine@ualberta.ca">wine@ualberta.ca</a></td>
<td>2015</td>
<td></td>
<td>2019-</td>
</tr>
<tr>
<td>Javier Martin de Carpi</td>
<td>Liaison for educational events, members’ lists, Porto representative in the GIC</td>
<td><a href="mailto:javiermartin@hsjdbcn.org">javiermartin@hsjdbcn.org</a></td>
<td>2010</td>
<td></td>
<td>2019-</td>
</tr>
</tbody>
</table>

Current and past Porto and the Interest group members-

See attached an excel spreadsheet of 35 members of the Porto group (one missing spot after Neil Shah has stepped down this year) and 73 members of the open Interest group (total of 108 members from 28 countries) (as of July 2019).

Past Porto group members

<table>
<thead>
<tr>
<th>Name</th>
<th>Country</th>
<th>Entrance Yr</th>
<th>Exit Yr</th>
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<tbody>
<tr>
<td>Yigael Finkel</td>
<td>Sweden</td>
<td>2004</td>
<td>2014</td>
</tr>
<tr>
<td>Kartazyna Bochanek</td>
<td>Poland</td>
<td>2004</td>
<td>2015</td>
</tr>
<tr>
<td>Izabella Lazowska</td>
<td>Poland</td>
<td>2004</td>
<td>2015</td>
</tr>
<tr>
<td>Eunice Trindade</td>
<td>Portugal</td>
<td>2005</td>
<td>2015</td>
</tr>
<tr>
<td>Sonny Chong</td>
<td>UK</td>
<td>2005</td>
<td>2015</td>
</tr>
<tr>
<td>Bhupinder Sandhu</td>
<td>UK</td>
<td>2004</td>
<td>2015</td>
</tr>
<tr>
<td>Salvatore Cucchiara</td>
<td>Italy</td>
<td>2004</td>
<td>2016</td>
</tr>
<tr>
<td>Anders Paerregaard</td>
<td>Denmark</td>
<td>2004</td>
<td>2016</td>
</tr>
<tr>
<td>Harland Winter</td>
<td>USA</td>
<td>2014</td>
<td>2017</td>
</tr>
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</table>
2. THE PORTO AND INTEREST GROUPS REMIT, STRUCTURE AND RULES including 2019 revisions
(Figure 1) See attached the revised Porto group charter

The “Paediatric IBD Porto Group” is a group of paediatric IBD experts from ESPGHAN whose goals are to generate collaborative international research and to provide a leadership role concerning current diagnosis and management of IBD in children. The Porto group is a closed group of elected members. The IBD Interest Group is an open group of ESPGHAN members who wishes to participate in all activities generated by the Porto group such as collaborative studies and guidelines preparation. The Porto group members are being elected from the Interest Group members.

**Aims**

1. **Research:** To perform collaborative research of all types as agreed within the group, including ongoing registries
2. **Guidelines:** To develop management guidelines and statements on behalf of ESPGHAN regarding paediatric IBD
3. **Advocacy:** To provide experts’ opinion and advocate on behalf of paediatric IBD patients when needed
4. **Education:** To improve medical care for children with IBD worldwide, by promoting good clinical practice via various educational tools, lectures and publications

**General**

1. Members of the Porto and the Interest Groups must be members of ESPGHAN.
2. When a site or center has one Porto member, no other person from this site can join the Porto group as a new member. Membership is not transferable to other colleagues from the same institution or other institutions, nor can observers vote by proxy for members. Sites that have had two members prior to April 2013 when this clause has been agreed upon, will continue to have two members until one steps down or is not re-elected.
3. Every member has one vote during ballots (voting for positions, new members, new initiatives etc). Every site has one vote (i.e. only one vote will be accepted from sites with two members).
4. Membership requires *active* participation in group activities. Members who have been absent for more than two consecutive annual meetings (three or more), and who have not participated in group activities for over two years (collaborative research, guidelines development etc), will no longer remain members, but may re-apply like other nominees.
5. Attendance of meetings and activities by observers may be allowed if cleared by the executive committee. These may include participants and research coordinators in relevant studies or historical members. The fee for observers will be decided by the executive committee and host as they are expected to cover their expenses. Observer status does not confer membership with the resulting rights and obligations as stated above. The arrangement of a meeting before/after the Porto meeting (e.g. the launch of a new study) is allowed if cleared by the executive committee, but finances have to be covered by the organizers of this meeting.
Elections

1. Three members of the Porto group will serve as an executive committee. Each committee member will be elected by secret ballot for a term of 3 years. One of these members will be elected specifically for the role of Chair of the group. No member may serve more than two consecutive terms on the committee.
2. The term of all elected (or re-elected) members will be for a period of 3 years only.
3. Total number of Porto group members will remain 36.
4. Each year 12 members will stand for re-election.
5. New members will be elected from the open IBD Interest Group of ESPGHAN.
6. Nominees are required to submit a CV, a personal statement why they should be elected to the Porto Group (1-2 paragraphs) and a statement what they would like to promote within the group if elected (1-2 paragraph).
7. Each eligible Porto group member will indicate which of the nominees (new and existing) should be elected according to the number of available slots (e.g. if 10 people compete for 5 slots, each member will indicate only 5 names). Nominees will be elected based on the cumulative points achieved by all voting members.
8. Members are expected to vote primarily according to the perceived merit to meet and promote the goals of the group. Geographic diversion will be also considered but as a secondary point.
9. Existing Porto members who are standing for re-election are allowed to vote for other nominees but not for themselves in order to leverage chances with nominees from the interest group.
10. Porto members will become “senior members” after the age of 65 to allow new member to take their place. Senior members are welcome to participate in the Porto group meetings as observers and are expected to cover all expenses related to their stay. Senior members reserve all rights as members of the open interest group.
11. **New clause:** At least three new members will join the Porto group each year. In cases where there are no 3 Interest group members selected, of the one third of the Porto group (12 members) standing for re-election each year, the three lowest ranked will step-down to the Interest group and the highest three ranked from the Interest group will be invited to the Porto group. Members of the Porto group who stepped down for other reasons (e.g. voluntarily or for seniority) will be included in the count of three members; For instance- if one became a senior member than only the lowest two will be forced to step down to the Interest group). The same will apply if there are less than 3 candidates from the interest group.

Open IBD Interest Group of ESPGHAN

1. The Open IBD Interest Group of ESPGHAN offers a forum to contribute to Paediatric IBD within ESPGHAN, even for those who are not members of the Porto group.
2. The Porto Group will hold an annual meeting with the Interest Group during the ESPGHAN annual meeting.
3. Registration to the Interest Group and its management will be through the executive committee of the Porto Group, to allow complete and useful coordination of activities.

4. ESPGHAN members who wish to join the IBD Interest group will register with the executive committee of the Porto group, using the same template as for the Porto group (CV, personal statement and planned activities). The membership will be then automatic.

5. Members of the IBD Interest group are expected to participate in the activities.

6. All Porto Group activities (except of the annual Porto group meeting) will also be open to the interest group, such as guidelines, statements, position papers and collaborative research. An open call to participate in all Porto Group projects will be issued to the interest group.

**Research**

1. Five members of the Porto group will serve as a research committee, including a chair, elected by the executive committee for 3 years (with the exception of the first term, which will be 2 years for 2 members, 3 years for the chair, and 4 years for 2 members to allow continuity). The main goal of the research committee is to promote, review, advise, and facilitate collaborative research, while ensuring excellence and impact.

2. Any member of the Porto and the Interest group may propose a research project to both groups by email and/or frontal presentation during the annual meeting; all proposals must be reviewed by the research committee prior to presentation/dissemination to the group.

3. The executive committee must ensure that every manuscript carrying the name of the Porto group is of sufficient merit, value and scientific rigor. This will be verified both at the time of the proposal submission and at conclusion of the study. Manuscripts will be approved by the executive committee for including the Porto group name prior to submission.

4. Each research project will be discussed in an annual meeting (at Porto or during the annual ESPGHAN meeting) to allow the entire group to vouch for the study as a Porto group paper. If such presentation is not feasible (e.g. desire to start the project prior to the meeting or unavailability of the authors to present), the executive committee may decide, based on recommendations from the research committee, on behalf of the group and the group’s approval will be obtained by email.

5. The Research Committee will review all research proposals submitted by Porto and Interest Group Members and will:
   a. Provide a critical review with specific comments on the protocol.
   b. Assess resubmissions, addressing comments by point-to-point reply (if needed), and submit a final recommendation (accept, resubmit revised proposal, reject) to the Executive committee to determine if the proposal can be a Porto group project.
   c. Proposals must be submitted to the secretary and research committee chair at least one month before the annual meeting for it to be discussed then, but proposals can also be approved throughout the year.
   d. To review the final manuscript prior to submission, provide comments, and submit a recommendation to the executive committee if the paper can carry the name of the Porto group and if it follows the rules outlined in this charter.

6. The proposal must include the following:
a. Subheadings: background and rationale, hypotheses, aims, explicit methods (design, eligibility criteria, outcomes, power calculation, statistical approach), and importance.

b. Authorship plan (in general balancing scientific merit, invested effort and number of included patients/samples from each site). In any case, each Porto group publication will include a full list of contributing members in an addendum to be listed as much as possible in Pubmed.

c. The anticipated reporting standard of the final manuscript (e.g. CONSORT, STARD etc- see last clause of this section).

7. Surveys and narrative reviews cannot typically be considered as Porto group projects.

8. Governed by the above restrictions (#3-5; all of which must apply), all manuscripts arising from the Porto group will have the name of the group in the title (Paediatric IBD Porto group of ESPGHAN). Author’s list will include as a suffix “on behalf of the Paediatric IBD Porto group of ESPGHAN”.

9. Research projects may be published in any journal according to the discretion of the co-authors. All manuscripts carrying the name of the Porto group will be reported according to accepted standards to ensure that the final reports are of highest possible quality.

Position papers and guidelines

1. Position papers and guidelines will be established according to ESPGHAN guidance following an open call to all members of the Porto and the Interest group.

2. Selection of members to participate in the projects will be decided (based on merit only) by the add-hoc committees nominated by the Porto Group.

3. The final voting reported in the manuscript will include the writing group and Porto group members. However, a pre-final version will be sent to the open Interest group members for comments.

4. Position papers and guidelines will be published in JPGN unless explicitly required otherwise (e.g. joint guidelines with ECCO).

3. SUMMARY OF ACTIVITIES IN THE LAST YEAR

As in recent years, the IBD Porto Group has been very active also this year and has concrete plans for the upcoming one.

The Group and Administration

1. The “research committee” we have established last year (see above updated charter) has been very active this year in reviewing research applications of the Porto and Interest groups members (Figure 3). The committee members are Eytan Wine (chair), with Sibylle Koletzko, Marina Aloi, Kaija Leena Kolho and Johan Van Limbergen. The committee reviews all submitted research proposal and in a peer review process suggests comments to the protocol and recommends to the group whether to endorse the submitted protocol as a Porto group project. Since its establishment, the committee received 21 proposals, 18 of which were reviewed (each by at least 3 reviewers; 3 were incomplete proposals so not
reviewed). All reviewed proposals were returned to applicants with comments, 2 were determined not to qualify as ‘Porto projects’ and 2 required major revisions and have not been resubmitted. Of the 15 presented in Porto or at ESPGHAN, 12 have been approved and are active projects (2 rejected; 1 deferred). These include 6 retrospective cohort studies, 4 prospective cohorts, and 2 RCTs. The committee also reviews the manuscripts and ensures it is of sufficient quality to carry the name of the Porto group.

2. This year Dror Shoval (Israel) was voted in instead of Sanja who stepped down. Neil Shah steeped down and not yet replaced.

3. To continue our effort for constant turnover of members from the interest to the Porto group, we revised the charter so that from 2019 every year 12 Porto members will stand for re-election (one third of the group). At least 3 of the 12 will step down and allow new 3 from the Interest group. This represents a forced turnover of at least ~10% and on average doubles the number of new members compared to the average annual rate during the previous 5 years.

4. The open IBD interest group of ESPGHAN is gaining more power and growing in numbers. Members of the interest group participate in all activities set forth by the Porto group (outlined below) and form the broader group from whom the Porto group members are elected.

Meetings

1. The annual 2-day meeting in Porto, Portugal (Feb 2019) where we reviewed ongoing activities and decided on the agenda for the upcoming year.

2. One joint update meeting of both the Interest and the Porto groups during ESPGHAN annual meeting in Glasgow (June 2019). Over 100 people attended this joint meeting, where ongoing projects and studies were reviewed.

3. Multiple email-discussions via two Google Groups.

Guidelines and statements (Figure 2)

Three guidelines and statements have been published in 2018 and one more in 2019 (see below publication list and Figure 2). Three more guidelines are currently ongoing:

1. IBD Unclassified guidelines. At the phase of draft.

2. Update of the ESPGHAN-ECCO CD guidelines- ongoing.

3. Adapting the Porto group guidelines to low resource countries- initiated.

Previously completed guidelines from the Porto Group (Figure 2)

1. “Updated bosimilars in PIBD”; JPGN 2019

2. “The use of endoscopy in PIBD”; JPGN 2018

3. “Updated ESPGHAN-ECCO joint UC guidelines” (Part 1: ambulatory and Part 2: Acute Severe Colitis); JPGN 2018

4. “Nutrition in PIBD”; JPGN 2018

5. “PIBD-Classes criteria for diagnosing Pediatric IBD”; JCC 2017

6. “Surgical Management of Crohn Disease in Children: Guidelines From the Paediatric IBD Porto Group of ESPGHAN”; JPGN 2017
“Use of Biosimilars in Paediatric Inflammatory Bowel Disease: A Position Statement of the ESPGHAN Paediatric IBD Porto Group”; JPGN 2015
9. “ESPGHAN Revised Porto Criteria for the Diagnosis of Inflammatory Bowel Disease in Children and Adolescents”; JPGN 2014
11. “Risk of Infection and Prevention in Paediatric Patients With IBD: ESPGHAN IBD Porto Group Commentary”; JPGN 2012

**Education**

1. We have successfully organized the 4th Paediatric IBD Masterclass for ~50 ESPGHAN delegates from 22 countries in Copenhagen (2018). The feedback was outstanding.
2. We are at the midst of organizing the 5th Paediatric IBD Masterclass in Malaga (2019), and voted on the next 2020 (Bristol) and 2021 (Russia- Low Resource County- see below) venues.
3. The IBD advanced course before the annual ESPGHAN meetings (one whole day) has now became a tradition when it was held for the fourth time in Glasgow. Over 250 delegates paid to participate in the program, which received excellent feedbacks. The aim of this course is to improve clinical skills in treating paediatric IBD in Europe.
4. PIBD is the largest and most important meeting worldwide on pediatric IBD. It is scheduled every 2 years and the last one was in last 2017 in Barcelona. With ESPGHAN we are at the midst of organizing the 2019 Budapest meeting, trying to overcoming challenges of being the first congress organized via Euro Congress.
5. Next PIBD congress will be held in Edinburgh 2021.
6. Symposia proposals for WCPGHN 2020 and for the advanced course have been submitted.

**Advocacy**

Gigi Veereman represented the Porto group in the EU parliament through various IBD activities.
We also participated in the ESPGHAN efforts during the annual IBD week.

**Promoting PIBD care in low resource countries**

In the last Porto group meeting (Feb 2019) the group discussed ways to promote PIBD care in LRC’s. Our guest to the meeting was Dr Mutaz Sultan from Palestine and he helped us to understand the barriers in treating PIBD when resources are limited. The group decided to proceed with several steps to facilitate care in LRC’s:

1. **Conferences:** Every other year, the PIBD masterclasses will be held in a low resource country (LRC); led by a Porto group member and local paediatric gastroenterologist. The first will be in 2021 in Russia (KLK with a local organizer).
2. **Education**: Revenues of the PIBD congress that are allocated to the Porto group per contract with ESPGHAN (50% of the profit) will be first allocated to a "Porto group scholarship for LRC:
   a. Two professorships/travel grants each year for Ped GI from LRC who wants to spend time in an IBD center of one of the Porto group members;
   b. Two travel grants to ESPGHAN annual meeting for Ped GI from LRC with a specific interest in PIBD (all this if there is profit).

3. **TelePortoPIBD**: Members of the Porto group will volunteer to provide one consult per month on difficult PIBD cases to LRC gastroenterologists (coordinated by Marina and Amit). The Porto group will fund a mini-web page to collect the applications. Christina will develop a LRC network to disseminate the opportunity.

4. **Position paper**: Has been initiated – how to use the Porto guidelines in low resource countries (50% of authors from LRC, many guests from outside ESPGHAN).

**Ongoing Original Research**

- **Lissy**: RAPID trial *under revision*
- **Lissy**: PRO-RAPID *New proposal – approved in ESPGHAN 2019*
- **Hankje**: EUROKIDS *active recruitment; ongoing study*
- **Arie**: UC diet *INDUCT; new study – approved in Porto, 2019*
- **Oren**: Endoscopic Dilatation in IBD *active recruitment*
- **Gemma**: STEP-CD *recruitment complete; manuscript in progress – to be presented at PIBD*
- **Annamaria**: CD features after UC surgery *recruitment complete*
- **Marina**: BioBank *recruiting; study funded by ESPGHAN*
- **Amit**: VEOIBD long term outcomes *new study – approved in Porto 2019*
- **Amit**: POPCORN *active recruitment*
- **Jiri**: Azathioprine failure *recruitment complete; preliminary result presented in Glasgow*
- **Jean Pierre**: anastomotic ulcers *recruitment complete; preliminary result presented in Glasgow*
- **Dan**: VEDOKIDS *recruitment ongoing*
- **Nadeem**: Allopurinol *recruitment complete; preliminary result presented in Glasgow*
- **Dror**: Isolated colonic CD *new study – approved in Porto 2019*
- **Dror & Marina**: Predicting response to anti-TNF *New proposal– approved in ESPGHAN 2019*
- **David**: MiniMARVEL *New proposal – approved in ESPGHAN 2019*

**Establishing a cross European PIBD Biobank (led by Marina Aloi and Holm Uhlig)**

We are at the midst of establishing a collaborative biobank of IBD children in Europe composed of children at disease onset (with controls) and before starting any biologics. Each site stores the samples locally but clinical data are collected centrally via an electronic CRF which has been completed to date. SOP’s have been agreed and submitted to ethics within the centers. Each site can propose ancillary studies to use the data and/or the samples and sites can elect to participate on a case by case basis and only then samples are shared. The first application for using the Biobank samples has been submitted by Dror Shoval.
List of publications arising from the Porto WG (average of ~5 (!!!) peer review manuscripts every year)


8. Joosse M, Aardoom M, Turner D...+35 authors....Levine A, de Ridder L. Malignancy and mortality in paediatric-onset inflammatory bowel disease: a 3-year prospective,


27. Levine A, de Bie CI, Turner D, Cucchiara S, Sladek M, Murphy MS, Escher JC; and the EUROKIDS Porto IBD Working Group of ESPGHAN. Atypical disease phenotypes in pediatric


**BUDGET 2019**

The GI Committee allocated to the Porto group for 2019 a flat sum of 10,000 €– operational budget (to be used for collaborative studies and annual meetings). In addition, there was a surplus of the Porto annual meeting from sponsorships. The surplus funds were added to the section of promoting collaborative projects.

<table>
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<tr>
<th>Expenses</th>
<th>Amount</th>
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<tr>
<td>Full payment hotel and meeting venue, Porto group meeting, February 21-23, 2019, Porto, Portugal - Accor hotel Ibis</td>
<td>2,081.80</td>
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<tr>
<td>Accommodation costs, Porto group meeting, February 23, 2019, Porto, Portugal - Accord Hotel Ibis Porto</td>
<td>105</td>
</tr>
<tr>
<td>Dinner costs, IBD Porto meeting, Feb 21-22, 2019 - J.A Dias</td>
<td>816</td>
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<tr>
<td>Travel refund, Guest Speaker, Porto Group annual PIBD meeting, March 22-23, 2019, Porto, Portugal - M. Sultan</td>
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<tr>
<td>Catering costs for IBD Porto Group Meeting Ordem Dos Medicos meeting room costs Ordem Dos Medicos IBD Porto Group meeting 2019</td>
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<tr>
<td>Total:</td>
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Sponsorship for Porto group meeting 2019-Pharmakern
Sponsorship for Porto group Meeting AbbVie

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**Net expenditure for meeting:** 2,125.23

Requests for operating funds for collaborative Porto projects:

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<td>1</td>
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<td>2</td>
<td>Dror &amp; Marina</td>
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<td>Sample shipping</td>
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<tr>
<td>3</td>
<td>Lissy</td>
<td>2,000</td>
<td>Sample collection and analysis</td>
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<tr>
<td>4</td>
<td>Eytan</td>
<td>2,500</td>
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<td><strong>TOTAL</strong></td>
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Total budget: €14,650 (including sponsorships for Porto meeting €4,650)

Total expenditure/requests: €16,595.23

**Total deficit/additional request: €1,945.23**

**BUDGET and REQUESTS for 2020**

**Planned activities**

1. **We request that another Masterclass will be held in 2020 in Bristol- chaired by Chris Spray, voted upon by the Porto group.**
2. **As every year we need the following meetings during ESPGHAN 2020 (Copenhagen):**
   a. A 4 hr slot for Guidelines Discussions (closed meeting)
   b. A separate (not overlapping with the advanced course and the guidelines) 2 hr business meeting of the Porto and the IBD Interest group (Open meeting) – please ensure a large room for at least 100 participants.
3. **Supporting the BioBank project**
4. **Continue the ongoing 17 collaborative studies.** A call to propose new collaborative projects will be announced early 2020 and discussed during Porto meeting in Jan 2020 and at the WCPGHAN 2020.
5. **Complete the ongoing guidelines.** New topics for guidelines will be determined during the Porto meeting in Feb 2020.
6. **Elections for 3 open slots and the chair (Dan Turner is stepping down after 6 years).**

**Budget Request for 2020**
The Porto group is the most prolific paediatric IBD group in the world. Beyond multiple multicentre research manuscripts carrying the name of ESPGHAN, the group's guidelines and position papers dictate global standards. We ask the GIC and the council to continue promoting this guaranteed investment.

In addition to funding for research and guidelines, we need funding to have our annual Porto meeting.

Porto members pay for the flights, and ESPGHAN/industry cover two hotel nights, meeting rooms, and meals.

We ask to continue the IBD Masterclass as an annual event. We believe these meetings are important to transfer IBD knowledge to all physicians and thus to improve the care children with IBD receive in Europe.

**Requested Budget**

**25,000 €— operational funds:**
- 2019 Porto meeting (8500 €)
- A guest speaker to Porto (1000 € for flight and two night hotel)
- Guidelines and meetings (2000 €)
- Promote collaborative projects (14,000 €):
  - Promote collaborative projects as per the projects progression, as per an open call (currently 17 ongoing)

**48,000 € - Paediatric IBD Masterclass**

Date completed: 16.7.19
FIGURES

Figure 1: Structure of the Interest and Porto groups

Figure 2

Guidelines and statements from the Porto group
Committee Activity 2018-2019

2018
• 11 proposals assessed (3 – general inquiries)
• 8 Reviewed
• 5 Accepted by RC and Porto
  • 1 Complete
  • 4 In progress
• 2 Rejected by Porto
• 1 Differed and resubmitted in 2019

2019
• 10 proposals submitted
• 10 proposals reviewed
• 2 were found not to qualify as Porto projects
• 1 requires major revisions before resubmission
• 4 Approved in Porto
• 3 new ones to be presented in Glasgow

Study Type

- RCT
- Prospective Cohort
- Retrospective Study

6
4

16