European Network for the Study of Cholangiocarcinoma (ENS-CCA)

Jesus M. Banales
Biodonostia Institute
San Sebastian (Spain)
FINANCIAL DISCLOSURE:
none

UNLABELED/UNAPPROVED USES DISCLOSURE: none
ENS-CCA

- Open, International and Multidisciplinary network of scientists focused on the study of CCA

- **Creation**: May 2015 (Vienna, Austria). 50th EASL Congress

**Main goal**

Promote and boost collaborative research projects on CCA at basic, translational and clinical level
Multidisciplinarity

**BASIC/TRASLATIONAL SCIENTISTS**
- Cholangiocyte pathobiology
- Molecular pathology
- Stem cells
- Genetics
- Epigenetics
- Quemorresistance
- Immunology

**CLINICIANS**
- Hepatologists/Gastroenterologists
- Oncologists
- Surgeons
- Radiologists
- **52 Research groups** (45 European; 7 USA)
- **14 European countries** (Austria, Denmark, France, Germany, Italy, The Netherlands, Lithuania, Norway, Portugal, Poland, Spain, Sweden, Switzerland and UK)
Steering Committee

Dr. Jesus M Banales
(Coordinator)
Biodonostia Institute
(San Sebastian; Spain)

Dr. Rocio R. Macias
Univ. Salamanca
(Salamanca; Spain)

Dr. Jesper B. Andersen
Biotech Research & Innovation Centre
(Copenhagen; Denmark)

Dr. Chiara Braconi
The Institute of Cancer Research
The Royal Marsden NHS Trust
(London; United Kingdom)

Dr. Domenico Alvaro
Sapienza Univ.
(Rome; Italy)

Dr. Vincenzo Cardinale
Sapienza Univ.
(Rome; Italy)

Dr. Guido Carpino
Sapienza Univ.
(Rome; Italy)
Objectives

1. Follow-up the **natural history** of CCA in European countries

2. Improve the current **CCA classification** (morphology, pattern of growth, genetics, epigenetics, molecular features, …)

3. **Risk factors** in the development and progression

4. Investigate on **early & non-invasive tumor biomarkers** for diagnosis and prognosis

5. Study the **molecular mechanisms of pathogenesis**

6. Compare effectiveness of **therapies**

7. Select patients for **clinical trials**
ENS-CCA consensus statement

Cholangiocarcinoma: current knowledge and future perspectives consensus statement from the European Network for the Study of Cholangiocarcinoma (ENS-CCA)


Special Issue on CCA (2019)

11 review articles in different disciplines

Guest Editor: Dr. Diego Calvisi
Editor: Dr. Mario Mondedi
**European CCA Registry**

**EASL Registry Award 2016**

Platform for collaborative research projects

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**Clinical & Biochemical data**

- **General data**
  - Demographic
  - Risk factors
  - Medical history

- **Clinical parameters**
  - Biochemical
  - Immunological
  - Diagnosis
  - Presentation
  - Staging
  - Treatment
  - Other tumors

- **CCA features**
  - Serum
  - Plasma
  - Bile
  - Urine
  - Tissue
  - Stools
  - Saliva

- **Collection of biological samples**
  - CCA histological classifications
  - Proliferation index
  - Tumor stroma extension
  - Microvessel density
  - Macrophage infiltration

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**Histological analysis**

- **CCA tissue**
  - Presence of pre-neoplastic lesions
  - Ductular reaction extension & proliferation
  - Peribiliary gland volume & proliferation

- **Surrounding tumor tissue**

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**Coordinators:** Dr. Jesus M Banales (Spain)  
Dr. Domenico Alvaro (Italy)

**Coordinator:** Dr. Guido Carpino (Italy)
European CCA Registry

Data collection

Start collection of data

2010

2016

2022

Start inclusion of data

Data analysis (~4,000 PTs)
European CCA Registry

1,916 CCA patients included
(16 Institutions)
ENS-CCA working groups

- WG-01 Basic Science
- WG-02 Histological and Morphological Characterization
- WG-03 Molecular Profiling
- WG-04 Exp. Therapeutics
- WG-05 Biomarkers, Diagnosis and Epidemiology
- WG-06 Clinical Trials
CCA Histological Registry

Coordinator: Dr. Guido Carpino (Italy)

FFPE Tumor Tissue Samples

**Target and needed Materials**
- Primary Target: **100 patients**
- Patients to be included should have: *frozen samples, blood, urine*
- Blank (FFPE) slides: 15

**Other ENS-CCA group member(s) interested in re-viewing the CCA slides:**
- Hermanns H (Würzburg, Germany)
- Evert M (Regensburg, Germany)
- Kendall T (Edinburgh, UK)

**Digital Registry**
- On-line system

**Future International collaborative projects** (Genomic, Epigenetic, Metabolic, etc)
CCA Histological Registry

OUTPUTS FROM CCA SPECIMENS

- CCA histological classification
- Tumor cell differentiation
- Proliferation Index
- Tumor stroma extension
- Microvessel density (MVD)
- Macrophage infiltration

VIRTUAL SLIDES FOR EACH PATIENT

Histo-morphological routine stains
Immunohistochemistry
CCA Histological Registry

VIRTUAL SLIDE: VIEW AND NAVIGATION
CCA Histological Registry

VIRTUAL SLIDE: VIEW AND NAVIGATION
### CCA Histological Registry

#### OUTPUTS FROM CCA SPECIMENS
- Example of automated count
  - Proliferation Index

#### Image automated analysis

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GWAS in CCA

**Coordinator:** Dr. Lewis Roberts (Mayo Clinic, Rochester, USA)

- 2000 CCA
- 500 Gallbladder cancer

**SNPs Genotyping**
National Cancer Institute (NCI, USA)

**NEXT:** Validation Phase (ongoing)
### ESCALON (2019-2013)

**European-Latin American network for the assessment of biomarkers to predict and diagnose hepatobiliary malignancies and characterization of risk factors for cancer development**

<table>
<thead>
<tr>
<th>Participant No</th>
<th>Participant organisation name</th>
<th>Short name</th>
<th>Country</th>
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<tr>
<td>1 (Coordinator)</td>
<td>Erasmus University Medical Center Rotterdam</td>
<td>EMC</td>
<td>The Netherlands</td>
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<tr>
<td>2</td>
<td>Biodonostia Health Research Institute, San Sebastian</td>
<td>BHRI</td>
<td>Spain</td>
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<tr>
<td>3</td>
<td>Universidad San Francisco de Quito</td>
<td>USFQ</td>
<td>Ecuador</td>
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<td>4</td>
<td>Hospital Privado Centro Médico de Córdoba</td>
<td>HPCMC</td>
<td>Argentina</td>
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<tr>
<td>5</td>
<td>Centro de Enfermedades Hepáticas Y Digestivas, Bogota</td>
<td>CEHYD</td>
<td>Colombia</td>
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<tr>
<td>6</td>
<td>Hospital Nacional Edgardo Rebagliati Martins, Lima</td>
<td>HNERM</td>
<td>Peru</td>
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<tr>
<td>7</td>
<td>Universidade Federal de Ciências da Saúde de Porto Alegre</td>
<td>UFCSPA</td>
<td>Brazil</td>
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<td>8</td>
<td>Pontificia Universidad Catolica de Chile</td>
<td>PUC</td>
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<td>University Health Network, Toronto</td>
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<td>Mayo Clinic, Rochester</td>
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<td>USA</td>
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<td>11</td>
<td>The Christie NHS Foundation Trust, Manchester</td>
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<td>Medizinische Hochschule Hannover</td>
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<td>The Netherlands</td>
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</table>

**WP leaders**

- Dr. Andre Boonstra (HCC)
- Dr. José Debes (CCA)
- Dr. Jesus Banales (GbC)

**New Registry databases in Latin America**
A scientific network officially endorsed by EASL
COLLABORATIONS
IPSCSG - ENSCCA

Coordinators: Dr. Cyriel Ponsioen
Dr. Ulrich Beuers
(Amsterdam, The Netherlands)

IPSCSG: Malignancies working group
Chairs: Luca Fabris and Jesus Banales
Establishing a global voice in cholangiocarcinoma through community collaborations
I Biennial ENS-CCA Congress

San Sebastian 2016 (Spain)

I International Monothematic Congress in Cholangiocarcinoma

Local Organizer: Dr. Jesus Banales
II Biannual ENS-CCA Congress

Rome 2018 (Italy)

Local Organizer: Dr. Domenico Alvaro
III Biannual ENS-CCA Congress

Edinburgh 2020 (UK)

Organizing Committee:

**Edinburgh**
Dr. Luke Boulter
Dr. Tim Kendall

**Manchester**
Dr. Juan Valle
Dr. Angela Lamarca

**London**
Dr. John Bridgewater
Dr. Chiara Braconi
Dr. Shahid Khan

**UK**
Mrs Helen Morement,
AMMF–The CCA Charity
European H2020 COST ACTION

**Aim:** creation of European Networks on science and technology

- 13 countries → 41 Institutions → 87 proposers
Subject: Memorandum of Understanding for the implementation of the COST Action “EUROPEAN CHOLANGIOCARCINOMA NETWORK” (EURO-CHOLANGIO-NET) CA18122

- [https://www.cost.eu/actions/CA18122](https://www.cost.eu/actions/CA18122)
- Awarded: 2019-2013 (4 years: 500,000 €)
- First Management Commettee Meeting (Brussels) on 18th March 2019: definition of the timeline of the COST Program

Coordinator: Dr. Vincenzo Cardinale
Dr. Jesus M Banales (Vice-Chair of COST Action)
Biodonostia Institute
(San Sebastian; Spain)
Overview

• COST Association General Info
• Application History
• The Challenge and the Rationale
• AIMs
• Constitution of EURO-CHOLANGIO-NET
• Main Deliverables
• What is going on (First Year Events)
COST provides networking opportunities for researchers and innovators in order to strengthen Europe’s capacity to address scientific, technological and societal challenges. COST implements its mission by funding bottom-up, excellence-driven, open and inclusive networks for peaceful purposes in all areas of science and technology.
COST Actions

- All fields of S&T
- All countries
- All career stages
- All Partners

Open to

- Trans-, multi-, interdisciplinarity
- COST Countries
- Global cooperation
- Young and experienced researchers
- Academia, public organisations, SME
- NGO, Industry, International Organisations
Encourage and enable researchers from less research-intensive countries across the COST Member Countries to set up and/or join COST Actions and get more intensively involved in all COST activities.

*Minum 5 cost members*
How COST Member Countries join an Action

Less than one year after CSO* approval of the Action

- Researcher contacts the CNC+
- CNC nominates MC Member
- CNC accepts the MoU

More than one year after CSO* approval of the Action, the MC must approve the new COST country request for participation in the Action

Date of CSO approval for 2018-1: 13/11/2018

*CSO: Committee of Senior Officials
+CNC: COST National Coordinator
How IPCs, NNCs and Specific Organisation join an Action

1. Entity already included in the proposal = Founders
   - After 1st MC: Chair encodes mutual benefit
   - Chair initiates MC approval in e-COST or confirms approval made during 1st MC meeting

2. New Entity
   - Chair encodes applicant details in e-COST
   - Applicant and Chair complete application form in e-COST
   - Online approval by MC and COST Association

- Once the Institution is approved the applicant becomes MC Observer
COST Policies

- Geographical coverage
- Early career investigators
- Gender
- Excellence & inclusiveness
- International cooperation
- SME & industry cooperation

COST Action
COST Actions

Memorandum of Understanding

4 years

Min 7 countries, average participation, 27 countries

Network

Research coordination and capacity building activities

~500,000 euros over lifetime
Networking tools

- Management Committee meeting
- Working Group meeting
- Conferences
- Training Schools
- Dissemination
- Scientific Term Scientific Missions (inter-lab exchanges)
- ITC Conference Grants

Research coordination & Capacity building activities
E-CHOLANGIO-BUILDING Action

- June 2016 – 1° ENSCCA meeting/Original idea
- December 2016 – First application Submitted
- June 2017 – Response (50/65 points)
- May 2018 – Second Application Submitted

E-CHOLANGIO-BUILDING Action aims to develop an orchestrated multidisciplinary international activity grid, organized in sub-action Working Groups dedicated to face interrelated challenges.
Although 3 countries are more represented, it should be noted that these countries have a larger population. However, the Action will be open to the incorporation of additional institutions and member especially from ICT and near-neighbour countries.
Other issues on the network composition

• The proposal would benefit from certain improvements: The proposal does not include Near-Neighbor country institutions, European RTD organisations, International organisations.

  • European RTD organizations, SMEs
    Cytognos Spain
    OWL Metabolomics Spain
    Ability Pharma Spain
    Delcath UK

  • International organizations: EASL International Liver Foundation, Prof. Colombo

  • Cholangiocarcinoma Foundation charity based in the United States (US); AMMF, the UK’s only cholangiocarcinoma charity.
Gender balance

- The gender distribution is somewhat unbalanced (26.4% women). Only 8.33% of the COST Inclusiveness target countries are involved.

- Promote inclusion of women and their role in leading position.
Cholangiocarcinoma: relevance of a worldwide challenge

- **Underestimation** due to classification coding for CCA and terminology. Four ICD-10 sub codes agreed: incidence rate of **3.65/100,000**, mortality rate of **4.01/100,000** in England in 2013. The number of deaths for the CCA from 2010 to 2013 in England surpassed the ones for hepatocellular carcinoma (HCC) (7,743 vs. 6,899 deaths). *A Report from Public Health England, National Cancer Registration and Analysis Service.*

- **CCA is the most frequent cause of metastasis of unknown origin**, and thus further highlights how we still do not know the real burden of CCA. *Varadhachary GR* *Engl J Med.* 2014.


- **Reduction of the mortality rate from other malignancies** (19 types comprising breast, lung, colon, etc.) in **1990-2009** (US data), but the mortality rate for malignancies of liver and bile ducts increased by more than 40% and 60% in females and males, respectively. *Llovet JM. Nat Rev Clin Oncol.* 2015
Translation stays between current knowledge and future perspectives: an issue in CCA.

Multilevel heterogeneity and limited knowledge on causes:

• No data to develop early diagnosis and screenings
• Incomplete/heterogenous molecular landscape

CCA heterogeneity has limited the discovery of biomarkers and novel therapeutic options, hampering the development of tools for early diagnosis and effective treatment.

CCA constitutes a major challenge for researchers, clinicians, national health systems and society.

Coordinated multidisciplinary pan-European studies are lacking.
AIM

• To face cholangiocarcinoma burden and heterogeneity through the creation a co-operative, interdisciplinary pan-European network harmonising clinical investigators, basic scientists, charities, European RTD Organizations, SMEs, and National and European Institutions.
• November 2018 – MoU published on line
• Definition of Management Committee
• March 2019 – First Management Committee meeting
• April 2019 submission WBP first year
• 1 May – Action officially started
PROPOSAL APROVED BY THE MC

Action Chair: Vincenzo Cardinale (Italy)

Action Vice-Chair: Jesus Banales (Spain)

Working Group Leaders and Vice-Leaders

• WG1 Preclinical: Diego Calvisi (Germany), Laura Fourasier (France)
• WG2 In-Depth Histomorphological Phenotyping: Guido Carpino (Italy), Benjamin Goeppert (Germany)
• WG3 Molecular Profiling: Jesper Andersen (Denmark), Trine Foulserais (Norway)
• WG 4 Epidemiology, Clinical Characterization and Trials: Juan Valle (UK), Bas Groot Koerkamp (The Netherlands)
• WG5 Early Diagnostic Biomarkers: Rocio Macias (Spain), Marcin Krawczyk (Poland),
• WG6 Development of Novel Therapeutic Targets and Tools: Chiara Braconi (UK), Joachim Martens (Swiss)
• WG7 Legislation and Ethics: Cecilia Rodrigues (Portugal), Tadeja Rezen (Slovenia)
WG1. PRECLINICAL

<table>
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<th>Tasks &amp; Activities</th>
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<tbody>
<tr>
<td>• To review available experimental models of CCA and their usefulness for preclinical studies.</td>
</tr>
<tr>
<td>• To conduct workshops on experimental models of CCA, including organoids, either from resected tumours tissue, from resected lymph node or from bile.</td>
</tr>
<tr>
<td>• To generate a data registry based on standardized sheet forms.</td>
</tr>
<tr>
<td>• To deliver STSMs to ECIs with a focus on \textit{in vitro} and \textit{in vivo} models.</td>
</tr>
<tr>
<td>• To identify targets for therapies that will be available for further tests in preclinical experiments.</td>
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<tr>
<td>• To translate the scientific evidences into regulatory language, practices and recommendations.</td>
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WG2. IN-DEPTH HISTOMORPHOLOGICAL PHENOTYPING
See Histology Registry leaded by Guido Carpino

<table>
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<tbody>
<tr>
<td>• To collect samples and data to set up the digitalised European registry. To review current knowledge on CCA histology and clinical-pathology; To harmonize nomenclature, clinical measurements, definitions, classification and outcomes.</td>
</tr>
<tr>
<td>• To conduct workshops to discuss and validate data and outputs.</td>
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<tr>
<td>• To share collected data with other WGs, through the registry.</td>
</tr>
<tr>
<td>• To organize STSMs for ECIs with a focus of histomorphology.</td>
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WG3. MOLECULAR PROFILING

Tasks & Activities

• To define the transcriptome, proteome and metabolome of each CCA subtype.
• To define molecular profiling of each CCA subtype.

• Because there are no genome wide association studies (GWAS) for CCA, an important task will be to carry out a GWAS in genomic DNA (gDNA) from >2000 CCA patients.

WG4. EPIDEMIOLOGY AND CLINICAL CHARACTERIZATION AND TRIALS

See Clinical Registry leaded and presented by Jesus Banales

Tasks & Activities

The primary goal of the clinical-epidemiology data registry will be to establish a follow-up of the natural history of CCA in European countries:

• To determine the current management of patients and outcomes.
• To broaden the current CCA classification by introducing information about morphological, immunohistochemical, genetic and molecular parameters.
• To elucidate the role of environmental factors in the development and progression of CCA.
• To compare the effectiveness of different therapies (e.g., standardised surgical approaches).
• To select patients for clinical trials. To explore the access to clinical trial for patients, the patients’ outcomes and treatment strategies and consistency across countries.
• To propose guidelines on CCA management.
• To attract support for planning, setting-up and coordinating observational and interventional multicentre clinical trials in CCA.
WG5. EARLY DIAGNOSTIC BIOMARKERS
See Radiology Registry

- To carry out the analysis of CCA imaging data and correlations with data from the histomorphology, genomic and clinical-epidemiology registries.
- To establish the best imaging modality to detect early changes in the wall of the bile ducts.
- To explore new imaging biomarkers (i.e., texture analysis; diffusion-weighted imaging; perfusion analysis) to differentiate patients with benign structures versus patients with CCA.
- To correlate imaging biomarkers with histological subtypes, genomic profile (radiogenenomic analysis) or clinical presentation (e.g. CCA on primary sclerosing cholangitis versus CCA on cirrhosis/fibrosis).
- To determine new early biochemical tumour markers for screening, diagnosis and CCA prognosis.

WG6. DEVELOPMENT OF NOVEL THERAPEUTIC TOOLS

Tasks & Activities

- To identify molecular targets for the development of novel therapeutic approaches.
- To define the genetic signature of chemo-resistance in CCA.
- To incorporate well-defined experimental models of CCA to the evaluation of novel therapies.
- To harmonize the use of novel biomarkers of CCA with the screening of antitumour drugs and therapeutic strategies.
- To carry out pilot pre-clinical studies using already available and novel drugs and therapeutic strategies.
Grant Holder Institution

PROPOSAL Sapienza University of Rome (Italy)

Key Positions

• Grant Holder Scientific Representative/Legal Representative

Prof. Domenico Alvaro (Director of Departement of Translational and Precision Medicine)

• Grant Holder Financial Representative

• Grant Holder Manager (assisting financial representative, chairs and all in invitations, reimbursements, traveling, reports of activities).
Early Career Investigator and Gender-Balance Advisory Committee

• Timothy Kendal (UK) Coordinator
• Patricia Munoz-Garrido (Denmark) Co-Coordinator
• Angela Lamarca (UK)

Short Term Scientific Mission Manager and Committee

• Exchange visits to foster collaboration, contributing to the scientific objectives of the Actions and allowing participant to learn new techniques, to have access to data/instruments/methods not available in their own institution.
• Jose Marin (Spain) Manager
Leaders of horizontal activities/Stake Holders
Contact Points

Patient Association, Scientific Society, and Foundation Advisory Committee

• Helen Morement (UK) Chair
• Marco Marzioni (Italy) Chair

Industrial Advisory Committee

• Alejandro Forner (Spain) Coordinator
• Cedric Coulouarn (France) Co-Coordinator
Science Communication Manager and web site and dissemination committee

• The Science Communication Manager (SCM) promotes the dissemination of the information by means of Action website, media and social communication channels. He also takes care of the public image of the Action.

• Rui Castro (Portugal) SCM

• Website under construction
Modified from http://www.smartcats.eu
Main Deliverables Year 1

• **Special Issue on cholangiocarcinoma in a peer-reviewed international scientific journal covering all aspects of this disease, containing multiple State of art/Consensus review articles**

• **Standard Operating Procedures (SOPs) for the collection and storage of biological samples related to experimental models of cholangiocarcinoma and SOPs for the collection and storage of all biological samples (liver biopsy, serum, pasma, DNA, urine and stool) from cholangiocarcinoma patients.**

• **Educational materials from the first EURO-CHOLANGIO-NET Training School on the promises and hurdles of novel models of cholangiocarcinoma**

• **Educational materials on cholangiocarcinoma for patients (including clinical implications of diagnosis, available treatments as well as description of the potential side effects of therapies) to be adopted in several European countries with translation in local language.**
Deliverable Year 2

- Conference proceedings/Educational materials of the joint COST action General Meeting / ENSCCA Bi-Annual International Meeting which is to be held in 2020 in Edinburgh.

- Production of educational materials as result of the second year Training School for the development of skills related to diagnosis and management of cholangiocarcinoma.

- Publication of International Expert Consensus on cholangiocarcinoma.

- Publication of the genomic analyses resulting from international collaborative studies to which COST participating countries are contributing.

- Press release on the key findings discussed at the monothematic conference on histomorphology diagnosis and classification of cholangiocarcinoma to sensitise policy makers to the importance of proper classification and codification of cholangiocarcinomas.
COST TOOL Meetings: Core Group Meeting/Working Group Meeting/ MC Meeting
Malta 12-13/09; 90 participants (65 reimbursed)

EURO-CHOLANGIO-NET set-up meeting: A set-up Action meeting

• 1. A meeting to boost activity within the WGs and Committees and collaboration among WGs.
• 2. Prepare and discuss publication drafts
• 3. Prepare and discuss website contents
• 4. Prepare and discuss training school organization
• 5. Prepare and discuss SOPs
• 8. Update state of art of registries (Clinical/Epidemiology, Histologic, Radiologic, Experimental)
• 9. Implement collaboration with patients’ charities

PROGRAM will be disseminated soon along with invitation
COST TOOL Training School: EURO-CHOLANGIO-NET Basic and Translational Science Training School, Glasgow (UK), 18-20 March 2020, N. trainees 30

Training school in novel experimental models for cholangiocarcinoma: from ex vivo patients derived organoids to in vivo animal models.

Location: The University of Glasgow – Beatson Institute for Cancer School

Coordinators: Prof Chiara Braconi (Hosting) and Prof Diego Calvisi

PRACTICAL SESSIONS

• Interactive small group workshops at the BICR Group 1: Patients derived organoid cultures – Group 2: Mouse derived organoid cultures - Group 3: Co-cultures with CAF - Group 3- 3D printing to create niches for co-cultures - detecting cell movements - generation of an ECM frame to support organoid growth.

• Educational videos/operational issues in animal research - Hydrodynamic tail vein injection - Genetic strategies for in vivo modelling
COST TOOL: STSMs N. 5
Average cost per STSM(EUR): 2000 Euro
STSM is one of the major tool for starting and potentiating collaborations within the network.

• The participants eligible of the STSM will be performed with regularly deadlines posted in the EURO-CHOLANGIO-NET web site: prioritizing scientific excellence, participation of young researcher, gender equality and IT inclusion; the proposals must be strictly pertinent to the goals of the Action, with a special priorities for applications related to the development and dissemination of the Registries and main WG projects.
• If you need info on COAST or on EURO-CHOLANGIO-NET COST Action
• If you need slides
• If you want join
• .... just ask me

 vincenzo.cardinale@uniroma1.it
+39 3495601492

Thanks ENSCCA Friends
Thanks AMMFF
Thanks Everyone
Acknowledgements

EURO-CHOLANGIO-NET COST ACTION (2019-2013)

EASL REGISTRY DATABASE AWARDS 2016 and 2019

EASL SPONSORSHIP: Congress 2018
THANK YOU FOR YOUR ATTENTION