

Sample & Data Banking: regulations, organization and scientific aspects 17th-18th March 2020

CLIBI Laboratory and Complex Structure of Rare Skeletal Diseases
IRCCS Istituto Ortopedico Rizzoli, Bologna (ITALY)



March, 17th 2020

13:45 - 14:15 Registration

14:15 - 14:45 Welcome and introduction

Chairman **L. Sangiorgi**

14:45 - 15:35 Key lectures

- ▶ Italian IRCCS biobank mapping, M.N. Luciani
- ▶ Public-private interaction for biobanking, E. Steinfeldt

15:35 - 16:25 Regulations and ELSI aspects

- ▶ GDPR application in biobanking and registry ambit, M. Macilotti
- ▶ Informed Consent and Patient Engagement, D. Mascalzoni

16:25 - 16.50 Break

16:50 - 18:20 Hands on session (in Italian)

- ▶ Simulazione della spiegazione dell'informativa e della raccolta del Consenso Informato - Informing participants and seeking consent process simulation
- ▶ Facilitators: , S. Borroni, G. Merla, D. Mascalzoni

18:20 - 18:30 Wrap up and conclusions

March, 18th 2020

Chairman **L. Sangiorgi**

9:00 - 10:15 Interoperability and harmonization

- ▶ RD-CODE project, M. Hanauer
- ▶ Registries and biobanks: road map to interoperability, M. Roos
- ▶ Disease Registry & Biobank, Patient Association and Biopharmaceutical Company: a successful story, A. Majdi

10:15 - 11:05 EJP-RD

- ▶ EJP R-D, an introduction, D. Julkowska
- ▶ Pillar 2 of EJP-RD, A. Rath

11:05 - 11:30 ISO 20387:2018

- ▶ Presentation of the Standard, G. Dagher

11:30 - 11.45 Break

11:45 - 12:45 Hands on session (in Italian)

- ▶ Percorso del campione dal prelievo alla distribuzione: guida pratica (documenti, CI, tracciabilità, LIMS, specifiche tecniche e qualitative) - Biobanking process: from sampling to distribution
- ▶ Facilitators: C. Baldo, B. Parodi

12:45 - 13:00 Wrap up and conclusions
CME test and feedback questionnaire

SCIENTIFIC INFORMATION

OFFICIAL LANGUAGE

The official language of the meeting is **English** without simultaneous translation. We kindly ask to all speakers to prepare their slides in English.

RULES FOR SPEAKERS/TEACHERS/TUTORS

You need to provide a mandatory signed COI declaration. The speech will be subject to CME accreditation, therefore, we request compliance with the following rules:

- the teaching activity shall be objective, balanced and not influenced by direct or indirect interests of stakeholders with commercial interest;
- the supervisor/teacher shall not include in the activity any teaching advertising of any kind for specific products of medical interest, shall indicate only generic names of drugs, instruments, principals and not their trade names, even if related to the subject matter;
- the supervisor/teacher shall not project images covered by copyright, identifying images of drugs or equipment and images that can violate patient privacy.

AUDIOVISUAL EQUIPMENT

PC Projection (only PPT file on CD or on a memory stick, USB port or DVD) will be provided. Speakers are kindly requested to contact the Slide Center, located inside the meeting hall, at least one hour before their presentation in order to test all the audiovisual material.

The presentation will be forwarded through Local Area Network (LAN) directly to the Video Projector.

The use of personal laptop (MAC/PC) is allowed directly in the meeting hall, don't forget the adaptor for VGA cable; the speaker must check it with the technician well in advance.

Each Speaker shall collect their technical material at the end of the session or at the latest at the end of the day. The Organizing Secretariat accepts no responsibility for any lost audiovisual material that was not collected or left unattended.

Remember to adhere strictly to the time allotted for each presentation.

ATTENDANCE CERTIFICATE

At the end of the Course an attendance certificate will be given to all registered participants.

VARIATIONS

The Scientific and the Organizing Secretariats reserve the right to make any change to the program they deem necessary for scientific and/or technical reasons.

GENERAL INFORMATION

VENUE

IRCCS ISTITUTO ORTOPEDICO RIZZOLI - HALL VASARI
Via G. C. Pupilli, 1 - 40136 Bologna, Italy
Ph. +39 051 6366111 www.ior.it

REGISTRATION

Free registration. Course reserved for a maximum of 100 people.

The registration includes:

- attendance to all scientific sessions
- attendance certificate
- F&B provided during the scientific program

DEADLINE FOR REGISTRATION MARCH 6th, 2020

After this date you can enroll only at the meeting venue.

REGISTRATION FORM WILL BE AVAILABLE ONLY ON THE DEDICATED WEBSITE [CLICK HERE](#)

HOTEL ACCOMMODATION

On the occasion of the meeting have been provided incentive rates for participants at some hotels located near the Congress venue.

The list of the Hotels will be available on the dedicated website [CLICK HERE](#)

To make a reservation contact the hotel directly and refer to the agreement with Organizing Secretariat My Meeting for the "Sampling & Data Banking Course".

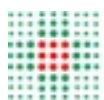
INSURANCE

Registration do not include insurance of any kind. It is strongly recommended that when your register for the Course and make your travel arrangements, you take out an insurance policy of your choice. The Organizing Secretariat cannot take any responsibility for any participant failing to arrange their own insurance. This insurance is to be purchased in your country of origin.

VISA

Some participants may need an entry VISA for Italy. Participants are requested to contact the Italian Embassy or Consulate in their home country or ask their travel agency for specific details relating to visa requirements.

It is the participant's responsibility of the participant to obtain a visa if required. For more information see the web site of the Italian Ministry of Foreign Affairs: http://www.esteri.it/visti/index_eng.asp





E.C.M.

Commissione Nazionale Formazione Continua



Educazione Continua in Medicina

Only for Italian Participants

Il Provider My Meeting n. 1396 ha assegnato **n. 7 crediti formativi ECM** per 7 ore di formazione RES per le seguenti categorie:

- ASSISTENTE SANITARIO
- BIOLOGO
- INFERMIERE
- INFERMIERE PEDIATRICO
- TECNICO SANITARIO DI LABORATORIO BIOMEDICO
- OSTETRICA/O
- CHIMICO disciplina: Chimica analitica
- FISICO disciplina: Fisica sanitaria
- MEDICO CHIRURGO discipline: Genetica Medica, Oncologia, Ortopedia e Traumatologia, Anatomia Patologica, Biochimica clinica, Laboratorio di genetica medica, Patologia clinica (laboratorio di analisi chimico-cliniche e microbiologia), Direzione medica di presidio ospedaliero, Epidemiologia
- PSICOLOGO discipline: Psicologia - Psicoterapia

L'accreditamento sarà effettuato per l'intero evento in un'unica soluzione.

Accreditamento Nazionale per n. 100 partecipanti certificati dal Provider My Meeting secondo le normative della CNFC pubblicate sul sito www.agenas.it.

L'attestato, conferente i crediti, sarà spedito via e-mail con posta certificata PEC ai partecipanti che avranno una presenza documentata di almeno il 90% sulla durata totale del percorso formativo accreditato e riconsegnato la documentazione relativa alla qualità percepita

Responsabile scientifico: Dr. Luca Sangiorgi

Obiettivo formativo tecnico professionale/di processo/di sistema n.18

Contenuti tecnico-professionali (conoscenze e competenze) specifici di ciascuna professione, di ciascuna specializzazione e di ciascuna attività ultraspecialistica, ivi incluse le malattie rare e la medicina di genere.

Obiettivi formativi generali:

L'evento si propone di accrescere le conoscenze nella gestione di una Biobanca e dei dati (o Registri di Patologia) ad essa correlati con particolare riferimento all'armonizzazione degli stessi ed al sistema di gestione della qualità, affrontando aspetti scientifici, organizzativo-gestionali, regolatori legati alla privacy e alla sicurezza dei campioni e dei dati.

Obiettivi formativi specifici:

maggiore conoscenza ed aggiornamento su tutti i principali aspetti del biobanking e una maggiore comprensione del valore di dati strutturati, di Registri di Patologia, della loro fruibilità nei più svariati settori scientifici, data anche la presenza al corso dei maggiori esperti nel settore sul territorio italiano ed europeo. Tra gli obiettivi formativi specifici sono stati individuati alcuni aspetti che saranno particolarmente approfonditi: normativa ed etica (ELSI), interoperabilità ed armonizzazione e Norma ISO 20387:2018.

Privacy

Pursuant to General Data Protection Regulation (EU) 2016/679 ("GDPR") of the European Parliament and Council of 27 April 2016 and to art. 13 of Legislative Decree 196 of 30 June 2003 on data protection and privacy and free circulation of personal data, we wish to inform you of the following:

Data controller and processor: My Meeting Srl represented in person by Dr. Cristina Federici - Via 1° Maggio 33/35 - 40064 Ozzano dell'Emilia, Bologna, Italy. C. F. / P. IVA 02759781202 - Tel +39 051 796971 - e-mail: info@mymeetingsrl.com

Purpose of data processing: Your personal data freely communicated and acquired for this event will be electronically and manually processed in order to follow up requests and to document your participation in the event as well as to fulfill legal obligations. The data may be disclosed and provided to different, but well-identified subjects who, in various capacities, contribute to or participate in the event, as well as to the competent Authorities according to the provisions of law and, possibly, to AGENAS for CME purposes. With your specific consent, your data will be used to send a periodic newsletter updating you on events of interest organized by My Meeting.

Personal data storage: My Meeting Srl shall store your personal data for the time needed for the management of the above-mentioned activities and avoiding in any case long term storage and enabling the data subject to exercise their rights. Your personal data will be stored for 10 (ten) years, unless the data subject undertakes actions to confirm consent to the use of their personal data.

The signature placed on the "Registration Form" represents acknowledgement of this information and the above rights and entails consent to personal data processing and communication for the above-indicated purposes. Failure to consent will preclude participation in the event.

PCO and CME Provider Standard N.1396



My Meeting S.r.l.

Via 1° Maggio 33/35 - 40064 Ozzano dell'Emilia (BO), Italy Ph. +39 051 796971 - Fax +39 051 795270
info@mymeetingsrl.com - www.mymeetingsrl.com



SERVIZIO SANITARIO REGIONALE
EMILIA - ROMAGNA
Istituto Ortopedico Rizzoli di Bologna
Istituto di Ricovero e Cura a Carattere Scientifico



Dipartimento
Rizzoli
Research
Innovation
Technology



E.C.M.
Commissione Nazionale Formazione Continua

