9th BIC

milestones AND NEW PATHS

BIC INTERNATIONAL CONFERENCE
ROME, ITALY | 15 - 17 SEPTEMBER 2017

ORGANIZED BY

SCIENTIFIC COMMITTEE
P.M. Mannucci • F. Peyvandi • A.B. Federici • N. Ciavarella
Conference venue:
The Church Palace Hotel
Via Aurelia, 481 - 00165 Rome - Italy

CME accreditation:
The event is accredited for Italian (Agenas) and European (UEMS-EACCME) Continuing Medical Education with 19 credits.

- **European CME Provider:** SMC Media Srl
- **Italian CME Provider:** Euro Medical Service (ID #3765)

To claim your credits please read the instructions at [www.bic2017.org](http://www.bic2017.org)

On-site Secretariat is open at:

- **Thursday, 14 Sept.** 18:00-20:00
- **Saturday, 16 Sept.** 8:30-19:00
- **Friday, 15 Sept.** 7:30-18:30
- **Sunday, 17 Sept.** 8:30-18:00

Staff may be available beyond these hours and dates for transfer coordination.

ORGANIZING SECRETARIAT: SMC Media srl
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/www.bicinternationalconferencehemophilia

www.bic2017.org
This international conference, that takes place every three years in Italy and has reached the ninth edition, is focused upon the clinical and translational research of a group of rare disorders of the hemostatic system: **hemophilia, von Willebrand disease, rare bleeding disorders** and the **thrombotic microangiopathies** (such as: thrombotic thrombocytopenic purpura and hemolitic uremic syndrome). The invited speakers, from Europe, North America and Asia are among the **best experts** of these disorders, which are rare but of great relevance and clinical complexity.

We wish to welcome clinical and basic science researchers to the 9th BIC International Conference in Rome and look forward to interacting with them throughout the whole 3-day period.

**The Scientific Committee**
P.M. Mannucci, F. Peyvandi, A.B. Federici, N. Ciavarella
FRIDAY, 15th September

08.20 Welcome speech
Pier Mannuccio Mannucci, Flora Peyvandi, Augusto B. Federici, Nicola Ciavarella

SCIENTIFIC SESSION 1: Hemophilia
Chairs: Nicola Ciavarella (Italy), David Lillicrap (Canada)

08.30 Will severe hemophilia become more common in the future?
The effects of population demographics on the prevalence of hemophilia
Manuel Carcao (Canada)

09.00 Determinants of factor VIII inhibitor risk. Is von Willebrand factor a key factor?
David Lillicrap (Canada)

09.30 Endocytosis of factor VIII by antigen-presenting cells: roles of von Willebrand factor and complement
Sébastien Lacroix-Desmazes (France)

10.00 Paradigm shift of the treatment of hemophilia A by factor VIII mimicking bispecific antibody
Midori Shima (Japan)

10.30 The challenges of innovative therapeutic interventions in hemophilia
Louis M. Aledort (USA)

11.00 Break & Poster Session (see ePoster Programme for details)

SCIENTIFIC SESSION 2: Von Willebrand disease
Chairs: Giancarlo Castaman, Augusto B. Federici (Italy)

11.30 Von Willebrand factor regulation of blood vessel formation and function
Anna Maria Randi (UK)

12.00 Gastrointestinal bleeding in von Willebrand disease: an unresolved problem
Giancarlo Castaman (Italy)

12.30 The potential use of nanobodies in the treatment of von Willebrand disease and hemophilia
Peter Lenting (France)

13.00 Lunch & Poster Session (see ePoster Programme for details)
**ORAL COMMUNICATIONS**

14.30 **Desmopressin (DDVAP): 40 years after**  
*Chairs: Massimo Franchini, Pier Mannuccio Mannucci (Italy)*  
- Pharmacokinetic modelling to predict FVIII:C response to desmopressin and its reproducibility in non-severe hemophilia A patients  
  *Lisette Schütte (the Netherlands)*  
- Perioperative management of von Willebrand patients with desmopressin; Towards a predictive population PK model  
  *Jessica Heijdra (the Netherlands)*  
- The effect of F8 missense mutations on individual pharmacokinetic parameters of DDAVP response in nonsevere hemophilia A  
  *Janneke Loomans (the Netherlands)*  
- The intracellular binding of FVIII to VWF may allow a clinically useful response to DDAVP in patients with hemophilia A due to FVIII mutations impairing FVIII binding to VWF  
  *Marc Jacquemin (Belgium)*  
- Desmopressin in moderate hemophilia A patients: a treatment worth considering  
  *Janneke Loomans (the Netherlands)*  
- Safety and effectiveness of desmopressin for the management of bleeds, delivery and major surgery in mild-moderate von Willebrand disease: Results of the Pro-Des-Wil study in a cohort of 84 patients  
  *Augusto Federici (Italy)*

**SATELLITE SYMPOSIUM**

15.30 **Satellite Symposium (not accredited for CME) Sponsored by Sobi**  
*Chairs: Stefan Lethagen, Stephen James*  
- Beyond half-life extension: characterising how rFVIIIFc impacts the immune system  
  - Welcome and Introduction  
  *Stefan Lethagen, Sobi™ (Sweden)*  
  - Retrospective Real World Analysis of Haemophilia A Patients with Inhibitors Treated with rFVIIIFc for Immune Tolerance Induction  
  *Jennifer Dumont, Bioverativ™ (USA)*  
  - Elucidating rFVIIIFc Interactions with the Immune System  
  *Katalin Kis-Toth, Bioverativ™ (USA)*  
  - MHC Class II Presentation of Fc Tregitope and FVIII Epitopes in rFVIIIFc: Potential Implications for Tolerance  
  *Margareta Wikén, Sobi™ (Sweden)*  
- Questions & Answers and Closing Remarks  
  *Stephen James, Sobi™ (Sweden)*

16.30 **Break & Poster Session** (see ePoster Programme for details)

**SCIENTIFIC SESSION 3: Thrombotic Microangiopathies**  
*Chairs: Johanna Kremer Hovinga (Switzerland), Flora Peyvandi (Italy)*

17.00 **Mechanism of thrombotic microangiopathy: lesson from zebrafish to men**  
*X. Long Zheng (USA)*

17.30 **Differential diagnosis of thrombotic microangiopathies**  
*Jeffrey C. Laurence (USA)*

18.00 **Immune repertoire in acquired TTP**  
*Johanna Kremer Hovinga (Switzerland)*
SATURDAY, 16th September

SCIENTIFIC SESSION 4: Gene Therapies  
Chairs: Luigi Naldini, Flora Peyvandi (Italy)

09.00  Addressing vector immunogenicity in the development of AAV-based gene therapies for bleeding disorders  
Federico Mingozzi (France)

09.30  Liver-directed lentiviral gene therapy of hemophilia  
Luigi Naldini (Italy)

10.00  An update on UCL/St Jude Haemophilia studies: successes and obstacles ahead  
Amit Nathwani (UK)

10.30  Gene therapy in hemophilia A  
Wing Yen Wong (USA)

11.00  Break & Poster Session (see ePoster Programme for details)

SCIENTIFIC SESSION 5: Von Willebrand Factor  
Chairs: Pier Mannuccio Mannucci (Italy), Denisa Wagner (USA)

11.30  Von Willebrand factor in ischemic stroke  
Simon de Meyer (France)

12.00  Interplay between von Willebrand factor, ADAMTS13 and NETs  
Denisa Wagner (USA)

SATELLITE SYMPOSIA / LECTURES

12.30  Satellite Lecture (not accredited for CME) Sponsored by Roche  
Chair: David Lillicrap (Canada)  
Haemophilia A: can we raise our treatment expectations?  
Elena Santagostino (Italy)

13.00  Lunch & Poster Session (see ePoster Programme for details)

14.30  Satellite Lecture (not accredited for CME) Sponsored by Kedrion-LFB  
Chair: Johannes B. Oldenburg (Germany)  
How to choose FVIII products in newly treated patients with severe hemophilia A: before and after SIPPET  
Pier Mannuccio Mannucci (Italy)

15.00  Satellite Symposium (not accredited for CME) Sponsored by Shire  
Chair: Anna Randi (UK). Co-Chair: Alessandro Gringeri (Austria)  
Recombinant von Willebrand Factor: An Innovative Therapeutic Option for Difficult to Control Bleeds

Welcome & Introduction  
Anna Randi (UK)

Challenges, solutions, and role of recombinant von Willebrand Factor in difficult to control bleeds  
Andreas Tiede (Germany)

Peri-operative management with recombinant von Willebrand Factor in patients with VWD  
Flora Peyvandi (Italy)

The use of recombinant von Willebrand Factor in a real world setting  
Diane Nugent (USA)

Questions & Answers  
Anna Randi, Andreas Tiede, Flora Peyvandi, Diane Nugent, Alessandro Gringeri

Closing Remarks  
Alessandro Gringeri (Austria)

16.00  Break & Poster Session (see ePoster Programme for details)
SCIENTIFIC SESSION 6: Von Willebrand factor and disease
**Chairs:** Robert Montgomery, Zaverio M. Ruggeri (USA)

16.30 | Old concepts and new functions of von Willebrand factor: 2017
Zaverio M. Ruggeri (USA)

17.00 | Von Willebrand factor regulation and role in disease
José Lopez (USA)

17.30 | Collagen and von Willebrand factor interactions and beyond
Pamela Christopherson (USA)

18.00 | The genetics of von Willebrand disease
Ann Goodeve (UK)

18.30 | The many faces of thrombocytopenia in von Willebrand disease type 2B
Cécile Denis (France)

SUNDAY, 17th September

SCIENTIFIC SESSION 7: Side effects of replacement therapy
**Chairs:** Giovanni Di Minno (Italy), Frits R. Rosendaal (the Netherlands)

09.00 | Randomisation or real world data?
Frits R. Rosendaal (the Netherlands)

09.30 | Current prophylaxis regimens are delaying but not preventing onset of joint arthropathy
Johannes B. Oldenburg (Germany)

10.00 | Predictors of outcome in immune tolerance induction (ITI): the Italian Registry
Giovanni Di Minno (Italy)

10.30 | Do we need to monitor for neurological adverse events in hemophilia?
Michael Makris (UK)

11.00 | Break & Poster Session (see ePoster Programme for details)

ORAL COMMUNICATIONS SESSION

11.30 | Oral communications: Translational Science
**Chairs:** Sébastien Lacroix-Desmazes (France), Karen Vanhoorelbeke (Belgium)

- Towards a clinically relevant hybrid adenovirus-Sleeping Beauty transposon vector for gene therapy for von Willebrand disease
  Irina Portier (Belgium)

- Treatment of hemophilia A by injection of FVIII-encoding mRNA
  Jules Russick (France)

- Application of combined gene and cell therapy within an implantable therapeutic device for the treatment of severe haemophilia A
  Chiara Borsotti (Italy)

- Pharmacokinetic profile of rFVIIIFc-VWF-XTEN (BIVV001) protein in cynomolgus monkey generated from a large-scale manufacturing stable cell line
  Joe Salas (USA)

- Recombinant factor VIII Fc fusion protein exhibits immunomodulatory effects on antigen presenting cells
  Katalin Kis-Toth (USA)

- Scavenger-receptor stabilin-2 is a major regulator of mouse VWF propeptide clearance
  Orla Rawley (Canada)
An open conformation of ADAMTS13 is a hallmark of acute acquired thrombotic thrombocytopenic purpura
Elien Roose (Belgium)

Profiling of anti-ADAMTS13 antibodies derived from patients with acquired thrombotic thrombocytopenic purpura
Nuno Graca (the Netherlands)

The role of von Willebrand factor in experimental malaria-associated acute respiratory distress syndrome
Sirima Kraisin (Belgium)

13.00 Lunch & Poster Session (see ePoster Programme for details)

14.00 Oral communications: Clinical Science
Chairs: Jenny Goudemand (France), Reinhard Schneppenheim (Germany)

Fitusiran, an investigational RNAi therapeutic targeting antithrombin for the treatment of hemophilia A or B with and without inhibitors: Interim results from a Phase 2 extension study
Pratima Chowdary (UK)

“FEIBA Global Outcome study (FEIBA GO)” first data read-out: Real world bleeding frequency in inhibitors patients on prophylaxis with APCC
Roberto Crea (Austria)

A cumulative review on four decades of thrombo-embolic events reported with the use of activated prothrombin complex concentrate (APCC) in congenital hemophilia
Alessandro Gringeri (Austria)

Influence of variant VWF multimer patterns on the diagnosis of VWD type 2B
Reinhard Schneppenheim (Germany)

Comparing platelet-dependent von Willebrand factor activity assays in 661 patients with von Willebrand disease – from the WiN Study
Johan Boender (the Netherlands)

Is type 3 VWD an homogeneous group?
Jenny Goudemand (France)

SCIENTIFIC SESSION 8: Thrombotic thrombocytopenic purpura
Chairs: Dominique Meyer (France), Flora Peyvandi (Italy)

15.00 Emerging concepts in acquired thrombotic thrombocytopenic purpura
Karen Vanhoorelbeke (Belgium)

15.30 Immune recognition of ADAMTS13 in acquired thrombotic thrombocytopenic purpura (TTP)
Jan Voorberg (the Netherlands)

16.00 Thrombotic microangiopathies
Paul Coppo (France)

16.30 Break & Poster Session (see ePoster Programme for details)

SCIENTIFIC SESSION 9: Thrombotic thrombocytopenic purpura and hemolytic uremic syndrome
Chairs: Pier Mannuccio Mannucci, Giuseppe Remuzzi (Italy)

17.00 The most recent advances in atypical hemolytic uremic syndrome (aHUS) and thrombotic thrombocytopenic purpura (TTP) including complement and von Willebrand factor (VWF) complement interactions
Marina Noris, Giuseppe Remuzzi (Italy)

17.30 Treatment monitoring in the atypical hemolytic uremic syndrome (HUS)
Massimo Cugno (Italy)
FRIDAY, 15th September

11.00 Bleeding phenotype and target joints predict patients with zero bleeds given once-weekly prophylaxis with BAY 94-9027
E. Musi (Switzerland)

Comparing the one-stage and chromogenic assay: factor VIII activity assay discrepancy at baseline does not reflect assay discrepancy after desmopressin in non-severe hemophilia A patients
L. Schutte (the Netherlands)

Evaluation of a fully-automated chemiluminescent immunoassay for the rapid quantification of ADAMTS13 activity and the detection of ADAMTS13 inhibitors
M. Mirabet (Spain)

Immunoglobulin G subclass distribution of anti-ADAMTS13 antibodies and its association with HLA-DR-DQ haplotypes and clinical course in acquired thrombotic thrombocytopenic purpura
G. Sinkovits (Hungary)

13.00 BAY 1093884 target the Kunitz Domains 1 and 2 of TFPI and Blocks Its Function
P. Mathew (USA)

Congenital (hereditary) thrombotic thrombocytopenic purpura (cTTP [hTTP], Upshaw–Schulman Syndrome): Patient experience, conceptual framework, and patient-reported outcome (PRO) instrument development
B. Ewenstein (USA)

Unraveling anti-spacer immunoprofiles of acquired TTP patients using anti-idiotypic antibodies
A. S. Schelpe (Belgium)

Prevention of relapses in patients affected by acquired TTP undergoing elective surgery
B. Ferrari (Italy)

13.30 Preliminary enrolment data from the U.S. post-marketing safety (PMS) study of rpFVIII in patients with acquired hemophilia
R. Crea (Austria)

POSSIBLE REPEAT TIME

14.00 Nonacog beta pegol for the prophylactic treatment of children with hemophilia B: interim results from the paradigm™5 clinical trial
M. Lapecorella (Italy)

POSSIBLE REPEAT TIME

14.15 Nonacog beta pegol in adult and paediatric patients: pooled data from the paradigm™ clinical programme
M. Lapecorella (Italy)

POSSIBLE REPEAT TIME
<table>
<thead>
<tr>
<th>Time</th>
<th>Title</th>
<th>Authors/Details</th>
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<tbody>
<tr>
<td>16.30</td>
<td>Clustered <em>F8</em> missense mutations cause hemophilia A phenotypic heterogeneity by combination of altered splicing, protein secretion and activity</td>
<td>M. Pinotti (Italy)</td>
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<td>16.45</td>
<td>Von Willebrand factor levels in patients with hemophilia</td>
<td>A. M. Milos (Croatia)</td>
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<td>Diagnosis of Upshaw-Schulman syndrome in adulthood</td>
<td>B. Ferrari (Italy)</td>
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<td>Modeling-guided identification of structural determinants contributing to conformational changes within ADAMTS13</td>
<td>B. Ercig (the Netherlands)</td>
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<td><strong>SATURDAY, 16th September</strong></td>
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<td>11.00</td>
<td>Whole exome sequencing as a first tier test in diagnosing primary bleeding disorders: WES First</td>
<td>Y. Smit (the Netherlands)</td>
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<td>11.15</td>
<td>The rare coagulation factor deficiencies: Single centre experience</td>
<td>F. D. Koseoglu (Turkey)</td>
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<td>11.15</td>
<td>Quantitative ELISA assay for in vivo proteolysis of von Willebrand factor and bleeding: A pilot study in type 2A(IIA) von Willebrand disease</td>
<td>S. Susen (France)</td>
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<td>Development of a gene therapy strategy for von Willebrand disease based on dual adeno-associated virus vectors</td>
<td>E. Barbon (France)</td>
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<td>13.00</td>
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<td>13.15</td>
<td>Effectiveness and safety of rFVIIa in paediatric Glanzmann Thrombasthenia patients: data from the international Glanzmann Thrombasthenia Registry</td>
<td>A. Roveda (Italy)</td>
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<td>13.30</td>
<td>Rare bleeding disorders in the Netherlands</td>
<td>J. Saes (the Netherlands)</td>
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<td>13.30</td>
<td>Laboratory diagnosis of von Willebrand disease type 2A versus LVAD-induced acquired von Willebrand syndrome</td>
<td>S. Deconinck (Belgium)</td>
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<td>14.00</td>
<td>Simultaneous measurement of thrombin and plasmin generation in patients with Factor XI deficiency</td>
<td>J. Saes (the Netherlands)</td>
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<td>14.00</td>
<td>Differential diagnosis between type 2A and 2B VWD in a 2-years old female child with a <em>de novo</em> novel mutation</td>
<td>M. T. Pagliari (Italy)</td>
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<td>14.00</td>
<td>Platelet function analyzer measurement of closure time as a biomarker for activity of high and ultralarge multimers of recombinant von Willebrand factor (rVWF)</td>
<td>P. Turecek (Austria)</td>
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SUNDAY, 17th September

11.00 Development of inhibitors in PUPs: Different scenario, same outcome
S. Trakymiene (Lithuania)

11.15 A novel macrophage-mediated pathway regulates enhanced clearance of hyposialylated von Willebrand factor in vivo
J. O’Sullivan (Ireland)

13.00 Stabilin-2 deficiency increases procoagulant activity and deep vein thrombosis in mice
A. Michels (Canada)

13.15 Enhanced local disorder in a clinically elusive von Willebrand factor provokes high-affinity platelet clumping
M. Auton (USA)

13.30 A cell-based assay to quantify von Willebrand factor mutant binding to integrin \( \alpha IIb \beta 3 \)
M. A. Brehm (Germany)

14.00 Variability in blood outgrowth endothelial cell characteristics and related von Willebrand factor parameters
A. De Jong (the Netherlands)

14.15 POSSIBLE REPEAT TIME

16.00 Acquired factor V inhibition due to Bactrim therapy – A previously unreported cause of a rare coagulopathy
R. Gately (Australia)

16.15 Hepatitis C viral infection in patients with hemophilia; An experience of Ege Adult Haemophilia Center
F. D. Koseoglu (Turkey)

16.30 POSSIBLE REPEAT TIME

16.45 POSSIBLE REPEAT TIME

17.00 Life-threatening pregnancy-associated atypical haemolytic uraemic syndrome and its response to eculizumab
R. Gately (Australia)

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A. De Jong (the Netherlands)

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<tr>
<td>J. A. López</td>
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<td>Research Department of Haematology, Cancer Institute, Faculty of Medical Sciences, London, UK.</td>
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<td>M. Noris</td>
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<td>J. Oldenburg</td>
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<td>A. M. Randi</td>
<td>UK</td>
<td>Professor of Cardiovascular Medicine – Imperial Centre for Translational and Experimental Medicine – Imperial College London NHLI Vascular Sciences – Hammersmith Hospital – London, UK.</td>
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<td>G. Remuzzi</td>
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<td>Professor of Nephrology, University of Milan, Italy, Mario Negri Institute for Pharmacological Research – Centro Anna Maria Astori – Science and Technology Park “Kilometro Rosso”, Bergamo, Italy.</td>
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<tr>
<td>F. R. Rosendaal</td>
<td>THE NETHERLANDS</td>
<td>Professor of Clinical Epidemiology, Leiden University Medical Center, Leiden, the Netherlands.</td>
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<tr>
<td>Z. M. Ruggeri</td>
<td>USA</td>
<td>Department of Molecular and Experimental Medicine, Scripps Clinic, La Jolla (CA), USA.</td>
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<td>M. Shima</td>
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<td>K. Vanhoorelbeke</td>
<td>BELGIUM</td>
<td>Faculty of Science, Campus Kulak Kortrijk, KU Leuven Kortrijk, Belgium.</td>
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<td>J. Voorberg</td>
<td>THE NETHERLANDS</td>
<td>Department of Plasma Proteins – Sanquin Research and University of Amsterdam, Amsterdam, the Netherlands.</td>
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<tr>
<td>D. Wagner</td>
<td>USA</td>
<td>Edwin Cohn Professor of Pediatrics Center for Blood Research Professor of Pediatrics, Program in Cellular and Molecular Medicine and Div. of Hematology / Oncology. Boston Children’s Hospital. Harvard Medical School, Boston, USA.</td>
</tr>
<tr>
<td>W. Y. Wong</td>
<td>USA</td>
<td>BioMarin, USA.</td>
</tr>
<tr>
<td>X.L. Zheng</td>
<td>USA</td>
<td>Robert B. Adams Endowed Professor and Director, Laboratory Medicine - Interim Director, Informatics - Department of Pathology UAB, the University of Alabama at Birmingham, AL, USA.</td>
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Welcome dinner

Welcome Dinner will run continuously from 7.30 p.m. until late hours (approx. 11:00 p.m.) in order to welcome all incoming delegates to take in the first glimpse of the 9th BIC friendly atmosphere and a delicious bite. Come in as you arrive and enjoy.

Conference dinner + Officinalia et aromaticca game

For centuries, merchants, pilgrims and men of culture have flocked to the Eternal City, finding accommodation in the city’s monasteries, guesthouses and hospices. It is with this spirit that we offer the guests of the 9th BIC International Conference an unforgettable dinner in Trastevere, inside the cloister of a 15th-century hospice dedicated to the accommodation and care of travellers that was built by the Republic of Genoa to support its fellow citizens visiting Rome. In this cloister, you will be served a dinner featuring traditional Rome dishes, with each dish celebrating the simple raw ingredients that are cultivated in Rome and its surrounding areas and flavoured with the many traditional herbs that are native to the rich Mediterranean countryside. Just like in ancient times when hospices had on the premises a “pharmacy” of medicinal herbs, that evening we will recreate this ancient atmosphere and a botanist will explain to guests the different characteristics of the medicinal plants, native to the Mediterranean, and their use in both food and pharmacology.

- Bus pick up at 7.30 p.m. in the lobby of the Church Palace Hotel.

Arrivederci dinner

Informal seafood dinner on the beach, 20km away from the hotel on the Roman coast. The ideal setting for the last BIC team building competition, a beach volley match, and the final BIC competition award ceremony.

- Transfer provided from the Church Palace Hotel at 6.00 p.m.

Reserve your dinners at the Conference Secretariat
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RECOMBINANT VON WILLEBRAND FACTOR: AN INNOVATIVE THERAPEUTIC OPTION FOR DIFFICULT TO CONTROL BLEEDS

Saturday 16th September 2017 | 15:00 – 16:00
BIC International Conference 2017 | Room: Auditorium
The Church Palace Hotel, Rome, Italy

Chair:
Anna Randi

Co-Chair:
Alessandro Gringeri

Faculty:
Andreas Tiede
Flora Peyvandi
Diane Nugent