



Associazione Farmaceutici Industria  
Società Scientifica

# The Healthcare Industry in the Age of Artificial Intelligence

# 65<sup>o</sup>



## SIMPOSIO **EFI**

**RIMINI 10•11•12 JUNE 2026**

Under the patronage of



**PALACONGRESSI • ENTRANCE A**

Via della Fiera, 23 • Rimini (Italy)

**PROGRAMME**

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- **Salvatore Agostino Giammillari** - AFI - DMX Pharma
- **Giorgio Bruno** - AFI President
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- **Rita Brusa** - AFI
- **Marilena Carazzone** - AFI
- **Carla Caramella** - AFI - University of Pavia
- **Matteo Cerea** - AFI - University of Milan
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- **Bice Conti** - AFI - SITELF
- **Lorenzo Cottini** - AFI
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- **Luciano Gambini** - AFI
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- **Maria Luisa Nolli** - AFI - NCNbio
- **Andrea Oliva** - AFI - Viatrix
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- **Alessandro Regola** - Vice-President of AFI
- **Stefano Salmaso** - CRS - University of Padua
- **Francesca Selmin** - AFI - University of Milan

## ORGANIZING COMMITTEE

- **Giorgio Bruno** - AFI President
- **Emiliano Celli** - New Aurameeting

## THESIS COMMITTEE

### *Coordinator:*

- **Carla Caramella** - AFI - University of Pavia

### *Members:*

- **Marco Adami** - AFI
- **Nicola Realdon** - AFI - University of Verona
- **Francesca Selmin** - AFI - University of Milan

## POSTER COMMITTEE

### *Coordinator:*

- **Giovanni Boccardi** - AFI

### *Members:*

- **Bice Conti** - AFI - University of Pavia
- **Antonio Danese** - Comunicazione e stampa AFI - DV Informatica
- **Monica Gunetti** - AFI - Ospedale Pediatrico Bambino Gesù
- **Maria Luisa Nolli** - AFI - NCNbio
- **Alessandro Regola** - Vice-President of AFI

## ORGANIZING SECRETARIAT

- **Aldo Bernuzzi** - New Aurameeting
- **Mariangela Del Vecchio** - AFI - New Aurameeting
- **Bianca Mazzucco** - New Aurameeting
- **Cindy Paganoni** - New Aurameeting
- **Elena Pelosi** - New Aurameeting
- **Federica Polidoro** - New Aurameeting



AFI sincerely thanks the prestigious companies that, through their participation, contribute to the organization of the Symposium and provide attendees with comprehensive insight into their activities.

## N. BOOTH EXHIBITING COMPANIES

114	Abar S.p.A.
101	ADASOFT
29	Adeodata S.r.l.
110	Akkodis Italy S.r.l.
39	ALFATESTLAB
119-120	ALIPHARMA SRL
2	Alperia
69	Altea UP
109	ALTEN Italia
82	Altergon Italia S.r.l.
105	AM
141	ANEMOCYTE
36-53	ANTARES VISION GROUP
15	ANTON PAAR
30-31-32-33	ASCCA
108	ASEPTIC GROUP
1	AxFlow S.r.l.
83	Azelis
21	B & D Italia srl
152	BioTrends EM
80-81	Bluenext Srl
156	Blue Reply
95	BRAM-COR SPA
73	CAI are you ready?
68	Capsulit S.p.a.
45	CHEMSAFE Srl
26	CIT Biopharma Contract Packaging
47	CO.RA. S.r.l.
34	COMECER
127	Consorzio Profibus e Profinet Italia
65	CSV Life Science Group
131-132	Cytiva
30-31-32-33	Dagard Italia srl
52	DDA Quality Development for Industries
36-53	DE LAMA
43	Deerns Italia spa
145	DHL Supply Chain Italy
61	DI RENZO REGULATORY AFFAIRS
35	DMX PHARMA SpA
63	Ellab Srl
38	EMERSON
98	Endress+Hauser Italia Spa
142	Eureka InfoMed
149-150-151	Eurofins
8	EUROMED PHARMA SERVICES
84	EURPACK
94	EUSOFT SRL
93	Evolutivo.io
37	FARMADATI ITALIA SRL
36-53	Farmo Res
48	Farmol Health Care
136	Fette Compacting
7	Fine Foods & Pharmaceuticals N.T.M. S.p.A.
11-12-13	FLARER S.A.
30-31-32-33	Fortil Italia
125	FPS PHARMA
20	Grafibox Sud
60	GRUPPO SASI
30-31-32-33	Guarda Medical Srl
79	HELYX - Gruppo Tecniche Nuove
41	Hitachi Europe
112	Honeywell Life Sciences
90	HUMANITAS UNIVERSITY
67	I.G.B. srl
40	IBD srl
51	ICE S.p.A. - ABC Farmaceutici Division
154-155	IMA S.p.A.
138	IMCD Italia SpA
121-122	IQVIA
89	IRCCS Istituto Romagnolo per lo Studio dei Tumori "Dino Amadori" - IRST Srl

## EXHIBITION AREA

118	JSB Solutions
25	IWT Pharma
87-88	Körber Pharma Software
96	KYMOS GROUP
135	LabAnalysis Process Pharma
9 - 10	LABWARE
117	Laetus
30-31-32-33	Lesatec Srl
148	LifeBee   a ProductLife Group Company
46	LISAM
100	Lives International
85	LP Pharma
130	LS Academy
57-75	MAASI Enterprises
99	Mangini Life Sciences – Nicomac
22-23	MARCHESINI GROUP SPA
54	Masco Group s.p.a.
78	Mérieux NutriSciences
66	Microsphere
56	Mokalwer
59	Neutron Testing Lab
42	NEUMO
137	NORDTEST
28	OC SRL
134	OLD PHARMA International Srl
6	Omag SpA
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124	Orise Srl
30-31-32-33	Parteco srl
30-31-32-33	Particle Measuring System
106-107	PHA.SE. Engineering & Compliance Services
62	PHARMA PARTNERS a PALLADIO GROUP brand
30-31-32-33	Pohling
49	PRC TICINUM LAB SRL
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144	PROMOFLUID SRL
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97	PVS
116	QSTEP
72	QualiMetrix
140	QUASCENTA Pte. Ltd.
14	RATTIINOX
123	REDOX srl
153	RIGEL S.P.A.
115	ROFARMA ITALIA SRL
50	S4BT   PRAGMA4U
60	SafetyDrugs
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103	SCF MARKET ACCESS, REGULATORY AFFAIRS & CRO
22-23	SEA VISION
5	SenzaGen Group
58	ServiTecno srl
91	SKAN AG
113	SOITRA S.p.A.
97	SOLTECH
16	SPH GROUP
92	STERIGENICS
64	Steriline
74	STERITEK SPA
139	Swan Analitica
25	TECNILABO
74	TECNOSOFT srl
111	TEMA SINERGIE
44	TempAid Cold Chain Packaging
76	Testo S.p.A
71	Universal Pack srl
70	Vaisala
77	Validations & Technical Services
17	VAMFARMA
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55	ZETA GmbH

## The Healthcare Industry in the Age of Artificial Intelligence

The 65th AFI Symposium, entitled “The Healthcare Industry in the Age of Artificial Intelligence”, is scheduled to take place, as usual, at the Palacongressi in Rimini, from 10 to 12 June 2026.

**Artificial Intelligence** is now the central theme and symbol of an evolving world, capable of marking a clear break with the past. It is no longer just about digitalisation, but about the deep integration of technologies aimed at optimising internal processes, ensuring quality, speed and competitiveness. In the current context, **AI acts as a strategic lever** that transforms the entire drug lifecycle, from preclinical research to regulatory compliance.

This technology therefore represents not merely a technical innovation, but a genuine driving force for revolutionising the delivery of patient services, ensuring superior standards of efficiency, accessibility and quality of care. We are witnessing **the evolution of traditional knowledge** in this field which, through this new approach, is becoming the key factor in the sector’s **competitiveness**.

The work of doctors, researchers and healthcare professionals in general, which has historically been based on years of study and clinical experience, now finds an unprecedented ally in AI, which enables the instantaneous analysis of vast amounts of data, making it available for **timely diagnoses** and **personalised treatments**. This paradigm shift in knowledge management draws on specific technologies such as **Machine Learning** to improve diagnostic accuracy and optimise treatment protocols, the **Internet of Things (IoT)** to generate constant data streams from medical devices and sensors, **Blockchain** to ensure the security and integrity of shared sensitive data, and **Wearable Devices** for real-time monitoring and continuous remote management of chronic conditions.

However, the adoption of AI cannot be separated from the human factor. Investment in **digital skills** for all staff involved is a fundamental prerequisite for the healthcare industry to fully exploit the benefits offered by Artificial Intelligence, which also acts as a **catalyst for collaboration** between hospitals, laboratories and pharmaceutical companies. Thanks to integrated systems, information is shared quickly and securely, speeding up research and improving the overall coordination of care.

The transition towards an AI-enhanced healthcare ecosystem is therefore **transforming the entire sector**, making it more efficient, competitive and better equipped to meet the challenges of tomorrow, whilst ensuring a significant improvement in access to care and its overall effectiveness.

The **65th AFI Symposium** aims to serve as a forum for discussion on this highly topical issue, for those who share the common goal of creating a healthcare ecosystem that is not only technologically advanced, but also equitable, sustainable and strictly regulated, for the benefit of the patient.

This edition of the AFI Symposium will feature **14 scientific sessions, 2 keynote lectures** and numerous side events, including **7 company workshops**, to be held in person on Wednesday morning, as well as **poster sessions, start-up sessions** and the **Young Talents Contest**, with the participation of leading speakers from industry, universities, institutions and trade associations.

The Symposium will begin on Wednesday afternoon with a speech by Giorgio Bruno, President of AFI, followed by a **keynote lecture** delivered by Massimo Scaccabarozzi – Director of the ON RADAR Think Tank at the Menarini Foundation, Past President of Farmindustria and President of Menarini Biotech – who will focus on the Symposium’s theme. This will be followed by three scientific sessions on **Clinical Research, Biotech and Advanced Therapies, Pharmacovigilance** and **the Supply Chain**.

On Thursday morning, the sessions on **Production, Regulatory Affairs** (Part One), **Digital Health, PVV** and **Posters** will take place. During this final session, participants will be able to present the results of their work, and the best posters will be selected and awarded prizes; these will remain on display in the dedicated area for the entire duration of the Symposium.

On Thursday afternoon, Riccardo Zagaria will deliver the **keynote lecture**, followed by sessions on **Innovation, Raw Materials, Regulatory Affairs** (Part Two) and **CRS/SITELF Pharmaceutical Sciences**.

Finally, on Friday morning, it will be the turn of the sessions on **Medical Devices, Quality, HTA & Market Access**, followed by those dedicated to **Start-ups** and the **Young Talents Contest**.

## WEDNESDAY, JUNE 10

09.00 - 13.00	Registration of Symposium participants
09.00 - 10.00	Workshop registration (outside the meeting rooms)
10.00 - 12.30	<b>Workshops (free access upon mandatory registration)</b>
<b>Marina 2 room</b>	<ul style="list-style-type: none"> <li>• <b>Bonfiglioli Consulting – LAIF:</b> From Vision to Impact: AI and Digital Transformation in Core Pharma Processes</li> </ul>
<b>Borgo 1 room</b>	<ul style="list-style-type: none"> <li>• <b>CAI are you ready?:</b> Qualification and Operational Management of Aseptic Filling Lines for Risk Mitigation and Business Continuity. From Annex 1 to PDA Technical Guide No. 1 “Aseptic Filling”: regulatory interpretation and implementation of appropriate technologies</li> </ul>
<b>Lavatoio room</b>	<ul style="list-style-type: none"> <li>• <b>CONSORZIO PI ITALIA:</b> MTP (Module Type Package): Automation as a New Opportunity for the Pharmaceutical Industry to Reduce Production Costs</li> </ul>
<b>Parco 1 room</b>	<ul style="list-style-type: none"> <li>• <b>Masco Group with the participation of Pierrel and PAT WAY:</b> Solutions and Integration Approaches in Digitalization within Life Sciences Operations: Process Sustainability and Compliance Risks</li> </ul>
<b>Parco 2 room</b>	<ul style="list-style-type: none"> <li>• <b>NEOTRON with the participation of Innovatune and Sanofi:</b> Extractables &amp; Leachables: A Bridge Between Regulatory Compliance and Toxicological Safety in the Pharmaceutical and Biopharmaceutical Industry</li> </ul>
<b>Borgo 2 room</b>	<ul style="list-style-type: none"> <li>• <b>PHA.SE.:</b> NextGen ATMP Facility: Development of ATMP Products in Compliance through the Adoption of Innovative Technological Solutions, Artificial Intelligence, and Digital Transformation Processes</li> </ul>
<b>Marina 1 room</b>	<ul style="list-style-type: none"> <li>• <b>PTM CONSULTING:</b> Risk-Based Thinking as True Intelligence for the Pharmaceutical Industry</li> </ul>
13.30	<b>Opening of the 65th AFI Symposium (at the entrance of the exhibition area)</b>
12.30 - 14.00	<b>Networking Lunch</b>
14.00 - 15.00	<ul style="list-style-type: none"> <li>• Giorgio Bruno – AFI President <b>Welcome Address and Opening of the Symposium</b></li> </ul>
<b>Tempio room</b>	<ul style="list-style-type: none"> <li>• Massimo Scaccabarozzi – Director, ON RADAR Think Tank – Fondazione Menarini, Past President of Farindustria, President Menarini Biotech <b>Keynote Lecture</b> <b>The Healthcare Industry in the Age of Artificial Intelligence</b></li> </ul>

**Poster SESSION:** during the Symposium, posters will be displayed in designated areas and will be available for viewing throughout the entire duration of the event.

## TECHNICAL-SCIENTIFIC SESSIONS

- 15.15 - 18.30  
**Castello 1 room**
- SESSION I – CLINICAL RESEARCH  
**AI, RWE and new regulations: simplifying and innovating to enhance the competitiveness of Italian clinical research**
- 15.15 - 18.45  
**Tempio room**
- SESSION II – BIOTECH & ADVANCED THERAPIES  
**The digital world: challenges and opportunities for biotech drugs and advanced therapy medicinal products**
- 15.15 - 18.30  
**Castello 2 room**
- SESSION III – PHARMACOVIGILANCE  
**The evolution of important safety communications**
- 15.15 - 18.15  
**Arco room**
- SESSION IV – SUPPLY CHAIN  
**Traceability; GDP And AI application in the pHARmaceutical supply chain**
- 20.00
- WHITE & BLUE Beach Party at the beach of the Grand Hotel Rimini in cooperation with*



## THURSDAY, JUNE 11

- 09.00 - 13.20  
**Tempio room**
- SESSION V – PRODUCTION  
**The role of AI and new technologies in supporting pharmaceutical manufacturing**
- 09.00 - 13.00  
**Castello 2 room**
- SESSION VI – REGULATORY (PART I)  
**AI supporting the pharmaceutical sector from development to commercialization of medicinal products – pharmaceutical science, technology and regulation in a present-day future where human intelligence and artificial intelligence collaborate for health**
- 09.00- 13.00  
**Castello 1 room**
- SESSION VII – DIGITAL HEALTH  
**The impact of AI on the healthcare sector: how technologies are transforming the industry**
- 09.00 - 13.00  
**Arco room**
- SESSION VIII – PATIENT VOICE & VALUE (PVV)  
**The voice of AI serving the patient: towards new digital engagement models**
- 12.30 - 14.30  
**Foyer Arco room**
- POSTER SESSION  
**Dedicated space for oral poster presentations. One author of each poster will be present next to their poster to answer questions from participants regarding the presented work**
- 12.30 - 14.30
- Networking Lunch in cooperation with*
- 
- 14.00 - 14.45  
**Tempio room**
- Riccardo Zagaria – Equalia President  
**Keynote Lecture**  
**Strategic autonomy, sustainability and access to treatment: the European off-patent pharmaceutical industry in the context of the new global balance of power**
- 15.00 - 18.45  
**Tempio room**
- SESSION IX – INNOVATION  
**From digitalization to Artificial Intelligence**

- 15.00 - 17.30  
**Castello 1 room**
- SESSION X – RAW MATERIALS  
**Regulatory and technological developments in API production**
- 15.00 - 18.30  
**Castello 2 room**
- SESSION VI – REGULATORY (PART II)  
**AI supporting the pharmaceutical sector from development to commercialization of medicinal products – pharmaceutical science, technology and regulation in a present-day future where human intelligence and artificial intelligence collaborate for health**
- 15.00 - 19.00  
**Arco room**
- SESSION XI – PHARMACEUTICAL SCIENCES CRS/SITELF  
**Food supplements and foods for special medical purposes: scientific, technological and regulatory aspects**
- 20.00
- Symposium Gala Dinner  
at the Grand Hotel Rimini in cooperation with*



## FRIDAY, JUNE 12

- 09.30 - 12.30  
**Castello 2 room**
- SESSION XII – MEDICAL DEVICES  
**Impact of AI on professional roles in the Medical Devices sector**
- 09.00 - 13.00  
**Tempio room**
- SESSION XIII – QUALITY  
**Artificial Intelligence: a new ally in Quality Control and Quality Assurance processes**
- 09.00 - 13.00  
**Castello 1 room**
- SESSION XIV – HTA & MARKET ACCESS  
**The new era of HTA: from regulation to impact within the Italian healthcare system**
- 09.00 - 10.45  
**Arco room**
- START-UP SESSION  
**Start-ups, AI and future education**
- 11.30 - 13.30  
**Arco room**
- YOUNG TALENTS CONTEST SESSION
- 12.30 - 14.30
- Networking Lunch in cooperation with*



## The Healthcare Industry in the Age of Artificial Intelligence

- 09.00 - 13.00
  - 09.00 - 10.00
  - 10.00 - 12.30
  - 13.30
  - 12.30 - 14.00
- Registration of Symposium participants
  - Workshop registration (outside the meeting rooms)
  - **Workshop**
  - **Opening of the 65th AFI Symposium (at the entrance of the exhibition area)**
  - **Working Lunch**

### WORKSHOP PROGRAM

*Free admission upon mandatory registration  
by Tuesday, 9 June via the following link:*

[\*\*CLICK HERE\*\*](#)

*Participation in the workshops does not grant access to the Symposium's scientific sessions*

Coordinator: **Alessandro Regola – AFI Vice President**

- 09.00 - 10.00
  - **Participant registration (outside the meeting rooms)**
- 10.00 - 12.30
  - **Marina 2 room**
  - Workshop organized by **Bonfiglioli Consulting – LAIF**  
*From Vision to Impact: AI and Digital Transformation in Core Pharma Processes*
- 10.00 - 12.30
  - **Borgo 1 room**
  - Workshop organized by **CAI are you ready?**  
*Qualification and Operational Management of Aseptic Filling Lines for Risk Mitigation and Business Continuity. From Annex 1 to PDA Technical Guide No. 1 "Aseptic Filling": regulatory interpretation and implementation of appropriate technologies*
- 10.00 - 12.30
  - **Lavatoio room**
  - Workshop organized by **CONSORZIO PI ITALIA**  
*MTP (Module Type Package): Automation as a New Opportunity for the Pharmaceutical Industry to Reduce Production Costs*
- 10.00 - 12.30
  - **Parco 1 room**
  - Workshop organized by **Masco Group with the participation of Pierrel and PAT WAY**  
*Solutions and Integration Approaches in Digitalization within Life Sciences Operations: Process Sustainability and Compliance Risks*
- 10.00 - 12.30
  - **Parco 2 room**
  - Workshop organized by **NEOTRON with the participation of Innovatune and Sanofi**  
*Extractables & Leachables: A Bridge Between Regulatory Compliance and Toxicological Safety in the Pharmaceutical and Biopharmaceutical Industry*
- 10.00 - 12.30
  - **Borgo 2 room**
  - Workshop organized by **PHA.SE.**  
*NextGen ATMP Facility: Development of ATMP Products in Compliance through the Adoption of Innovative Technological Solutions, Artificial Intelligence, and Digital Transformation Processes*
- 10.00 - 12.30
  - **Marina 1 room**
  - Workshop organized by **PTM CONSULTING**  
*Risk-Based Thinking as True Intelligence for the Pharmaceutical Industry*
- 12.30 - 14.00
  - **Networking Lunch**

14.00 - 15.00  
Tempio room

- Giorgio Bruno – AFI President  
**Welcome address and opening of the Symposium**
  - Massimo Scaccabarozzi – Director, ON RADAR Think Tank, Fondazione Menarini – Past President of Farmindustria – President of Menarini Biotech  
**Keynote Lecture**  
**The Healthcare Industry in the Age of Artificial Intelligence**
- Technical-scientific sessions

## SESSION I

### AI, RWE E NUOVE NORME: SEMPLIFICARE E INNOVARE PER RENDERE LA RICERCA CLINICA ITALIANA PIÙ COMPETITIVA

#### Castello 1 room

- 15.15 - 15.30      **Introduction**
- Alessandra Ferrari – AFI – IRCCS Policlinico San Matteo Foundation, Pavia
  - Ilaria Maruti – AFI – Astrazeneca
- Moderators:**
- Alessandra Ferrari – AFI – IRCCS Policlinico San Matteo Foundation, Pavia
  - Ilaria Maruti – AFI – Astrazeneca
- 15.30 - 16.00      **EU AI Act and Italian AI legislation: what impact on clinical research**
- Silvia Stefanelli – AFI – Stefanelli Law Firm
- 16.00 - 16.30      **Evolution of information systems and related regulatory provisions**
- Sara Cazzaniga – AFI – IQVIA
  - Roberto Soj – Department for Digital Transformation, Presidency of the Council
- 16.30 - 17.15      **Coffee break**
- 17.15 - 18.15      **Round Table: Enhancing the competitiveness of clinical research in Italy: from the use of new technologies (including AI) to regulatory simplification**
- Moderators:**
- Arianna Avitabile – AFI – Eli Lilly Italia
  - Lorenzo Cottini – AFI
- Speakers:**
- Celeste Cagnazzo – President, GIDM
  - Marica Nobile – Federchimica Assobiotech
  - Elena Ottavianelli – AICRO
  - Mauro Racaniello – Farmindustria
  - Carlo Tomino – IRCCS San Raffaele, Rome
- 18.15 - 18.30      **Discussion and closing remarks**
- 20.00              **WHITE & BLUE Beach Party at the beach of the Grand Hotel Rimini in cooperation with**

**phase**

14.00 - 15.00  
**Tempio room**

- Giorgio Bruno – AFI President  
**Welcome address and opening of the Symposium**
  - Massimo Scaccabarozzi – Director, ON RADAR Think Tank, Fondazione Menarini – Past President of Farmindustria – President of Menarini Biotech  
**Keynote Lecture**  
**The Healthcare Industry in the Age of Artificial Intelligence**
- Technical-scientific sessions**

## SESSION II

### THE DIGITAL WORLD: CHALLENGES AND OPPORTUNITIES FOR BIOTECH DRUGS AND ADVANCED THERAPY MEDICINAL PRODUCTS

**Tempio room**

- Moderators:**
- Monica Gunetti – AFI – IRCCS Bambino Gesù Pediatric Hospital
  - Sara Vignati – AFI – AFTI – SUPSI
- 15.15 - 15.50      **Keynote Lecture: How Artificial Intelligence is Transforming Molecular Discovery**
- Alfonso Pozzan – AFI – Evotec Verona
- 15.50 - 16.10      **AI-driven optimization for lead compounds**
- Gianvito Grasso – InVirtuoLabs
- 16.10 - 16.30      **Artificial Intelligence in Biotech and Advanced Therapies: the regulatory authority perspective**
- Marco Paolo Fulfaro – AIFA (*to be confirmed*)
- 16.30 - 16.40      **From Guidance to Practice: How EU Regulators are shaping the use of AI in Biotech & ATMPs**
- Michela Gabaldo – AFI – Aptuit
- 16.40 - 17.15      **Coffee break**
- 17.15 - 17.35      **Facility ATMP Innovation: soluzioni compliant, intelligenti e sostenibili**
- Paolo Bosisio – AFI – PHA.SE.
  - Cristina Zanini – AFI – IWT PHARMA
- 17.35 - 18.30      **Round Table: Competitive advantage of Artificial Intelligence and new technologies in the development of Biotech drugs and Advanced Therapies**
- Moderators:**
- Paolo Barbanti – AFI – Pharma & Biotech Advisor
  - Maria Luisa Nolli – AFI – NCNbio
- Speakers:**
- Paolo Bosisio – AFI – PHA.SE.
  - Marco Paolo Fulfaro – AIFA (*to be confirmed*)
  - Claudia Maldini – AFI – Miltenyi Biotec
  - Alfonso Pozzan – AFI – Evotec Verona
  - Cristina Zanini – AFI – IWT PHARMA
- 18.30 - 18.45      **Discussion and closing remarks**
- Maria Luisa Nolli – AFI – NCNbio
- 20.00                **WHITE & BLUE Beach Party at the beach**  
**of the Grand Hotel Rimini in cooperation with**

**phase**

14.00 - 15.00  
Tempio room

- Giorgio Bruno – AFI President  
**Welcome address and opening of the Symposium**
  - Massimo Scaccabarozzi – Director, ON RADAR Think Tank, Fondazione Menarini – Past President of Farindustria – President of Menarini Biotech  
**Keynote Lecture**  
**The Healthcare Industry in the Age of Artificial Intelligence**
- Technical-scientific sessions

## SESSION III

### THE EVOLUTION OF IMPORTANT SAFETY COMMUNICATIONS

Castello 2 room

- 15.15 - 15.20      **Welcome and introduction**
- Andrea Oliva – AFI – Viatris
- Moderator:**      • Andrea Oliva – AFI – Viatris
- 15.20 - 15.50      **AIFA's perspective on Important Safety Communications**
- Laura Sottosanti – AIFA (*to be confirmed*)
- 15.50 - 16.30      **Engagement of healthcare professionals and patient associations: a dual interview**
- Federica Fedele – Presidente Associazione Vincere la Trombosi
  - Simonetta Palazzini – AUSL della Romagna
- 16.30 - 17.15      **Coffee break**
- 17.15 - 17.35      **Management of an Important Safety Communication within a pharmaceutical company**
- Amanda Mattavelli – AFI – Johnson & Johnson
  - Francesca Rollo – AFI – Doc Generici
- 17.35 - 18.15      **Round Table with the participation of:**
- Renato Garlaschini – Federchimica Assosalute
  - Giovanna Pescatore – Farindustria
  - Laura Sottosanti – AIFA (*to be confirmed*)
  - Romina Tulimiero – Egualea
- 18.15 - 18.30      **Discussion and closing remarks**
- 20.00                **WHITE & BLUE Beach Party at the beach of the Grand Hotel Rimini in cooperation with**



14.00 - 15.00  
**Tempio room**

- Giorgio Bruno – AFI President  
**Welcome address and opening of the Symposium**
  - Massimo Scaccabarozzi – Director, ON RADAR Think Tank, Fondazione Menarini – Past President of Farmindustria – President of Menarini Biotech  
**Keynote Lecture**  
**The Healthcare Industry in the Age of Artificial Intelligence**
- Technical-scientific sessions

## SESSION IV

### TRACEABILITY, GDP, AND AI APPLICATION IN THE PHARMACEUTICAL SUPPLY CHAIN

**Arco room**

- 15.15 - 15.30 **Welcome and introduction**
- Alberto Bartolini – AFI – CIT
  - Roberto de Luca – AFI – University of Padua
- Moderators:**
- Alberto Bartolini – AFI – CIT
  - Roberto de Luca – AFI – University of Padua
- 15.30 - 15.45 **Supply chain traceability: definition and implementation approaches**
- Alberto Bartolini – AFI – CIT
- 15.45 - 16.00 **Impact of GDP on pharmaceutical companies**
- Maurizio Riitano – AFI – Astrazeneca
- 16.00 - 16.15 **Impact of GDP on logistics operators**
- Sara Cernuschi – AFI – Euromed Pharma
- 16.15 - 16.30 **AI and advanced therapies: when logistics becomes part of the treatment**
- Alfredo Sassi – H-Ventures Group
- 16.30 - 17.15 **Coffee break**
- 17.15 - 17.35 **AI application project in pharmaceutical transport**
- Paolo Gagliardi – PHSE Group
- 17.35 - 18.00 **AI application project in pharmaceutical distribution**
- Iacopo Iacopini – Hippocrates Holding
  - Maria Assunta Sgro – Hippocrates Holding
- 18.00 - 18.15 **Discussion and closing remarks**
- 20.00 **WHITE & BLUE Beach Party at the beach  
of the Grand Hotel Rimini in cooperation with**

**phase**

## SESSION V

### THE SUPPORT OF AI AND NEW TECHNOLOGIES IN PHARMACEUTICAL MANUFACTURING

Tempio room

- 09.00 - 09.10 **Opening remarks**
- Lino Pontello – AFI
  - Vittorio Tonus – AFI
- Moderators:**
- Lino Pontello – AFI
  - Vittorio Tonus – AFI
- 09.10 - 09.40 **Sustainable investments for the reduction of economic and environmental risks in relation to new reporting requirements**
- Ettore Piantoni – AFI – CEN/CENELEC
- 09.40 - 10.00 **Role of companies in the evaluation and improvement of environmental performance indicators**
- Giorgio Amato – AFI – Techniconsult
- 10.00 - 10.25 **Italian serialization: first production experiences from the pilot phase**
- Sabina Gualazzini – AFI – DMX
- 10.25 - 10.50 **Serialisation in Italy: the roadmap leading up to 9 February 2027**
- Adriano Pietrosanto – Egualia
- 10.50 - 11.00 **Discussion**
- 11.00 - 11.30 **Coffee break**
- 11.30 - 11.50 **Modular techniques and Plug-and-Produce automation for the digital factory of the future**
- Marco Banti – ANIPLA
- 11.50 - 12.10 **Pharma Digital Twin: from retrospective control to predictive process management**
- Simone Guerrieri – GS Consulting
- 12.10 - 12.30 **Artificial Intelligence applied to visual inspection**
- Andrea Sardella – Brevetti-CEA
- 12.30 - 12.50 **How AI and Digital Innovation are revolutionizing strategies and maintenance**
- Marco Luppi – AFI – Marchesini
  - Daniele Puricelli – Zambon
- 12.50 - 13.10 **Spray Drying and innovative technologies to support complex formulations**
- Silvestro Lucariello – Microsphere
  - Andrea Tapparo – Microsphere
- 13.10 - 13.20 **Discussion and closing remarks**
- 13.20 - 14.30 **Networking Lunch in cooperation with**



**Omnia  
Technologies**  
Life Sciences

## SESSION VI – FIRST PART

### AI SUPPORTING THE PHARMACEUTICAL SECTOR FROM DEVELOPMENT TO COMMERCIALIZATION OF MEDICINAL PRODUCTS – PHARMACEUTICAL SCIENCE, TECHNOLOGY AND REGULATION IN A PRESENT-DAY FUTURE WHERE HUMAN AND ARTIFICIAL INTELLIGENCE COLLABORATE FOR HEALTH

Castello 2 room

- 09.00 - 09.05      **Opening remarks**
- Alessandra Molin Zan – AFI – Zentiva Italia

#### PRECLINICAL PHASE

- Moderators:**
- Manuela Monti – AFI – IRCSS Istituto Romagnolo per lo studio dei Tumori “Dino Amadori” IRST
  - Floriana Raso – AFI – Alfasigma

- 09.05 - 09.25      **Computational methods for protein studies: molecular simulations and AI**
- Domenico Scaramozzino – Karolinska Institutet Stoccolma

- 09.25 - 09.45      **Computational techniques for the study of medicinal plants**
- Giorgio Cappellucci – Università di Siena

- 09.45 - 10.05      **AI in radiopharmaceutical research and development**
- Daniela Chicco – Bridge4Pharma
  - Maurizio Franco Mariani – Bridge4Pharma

#### FROM PRECLINICAL TO CLINICAL

- Moderators:**
- Guido Fedele – AFI
  - Luciano Gambini – AFI

- 10.05 - 10.25      **Artificial Intelligence and its Preclinical Applications at Bayer Pharmaceuticals**
- Matteo Aldeghi – AFI – Bayer

- 10.25 - 10.45      **Transforming Clinical Research with AI**
- Tiziana Trombetti – AFI – Sanofi

- 10.45 - 11.30      **Coffee Break**

#### PRODUCTION PHASE

- Moderators:**
- Rita Brusa – AFI
  - Alessandro Regola – AFI Vice-President

- 11.30 - 11.50      **From algorithm to trust: how to validate AI vendors**
- Donato Migliarino – AFI – Farmaceutici Formenti (Grünenthal Group)

#### REGULATORY PHASE

- Moderators:**
- Francesca Berti – AFI – Eli Lilly Italia
  - Elena Trovati – AFI – Amgen

- 11.50 - 12.10      **AI in dossier assessment and decision-making processes**
- Francesca Pozzi – AFI – Zentiva Italia
  - Elena Tedeschi – AFI – Teva Italia

- 12.10 - 12.30      **How AI can support Medical Writers in drafting the Clinical Evaluation Report – Benefits and Risks**
- Daniela Zelaschi – AFI – Pharma Ideas

- 12.30 - 12.50      **AI in IMS**
- Claudia Calò – AFI – Chiesi Farmaceutici
  - Lorenza Castelli – AFI – Astellas Pharma

- 12.50 - 13.00      **Discussion and closing remarks**

- 13.00 - 14.30      **Networking Lunch in cooperation with**



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## SESSION VII

### THE IMPACT OF AI ON THE HEALTHCARE SECTOR: HOW TECHNOLOGIES ARE TRANSFORMING THE INDUSTRY

#### Castello 1 room

- 09.00 - 09.05      **Introduction**
- Massimo Beccaria – AFI – Advice Pharma
  - Sara Cazzaniga – AFI – IQVIA
- Moderators:**
- Massimo Beccaria – AFI – Advice Pharma
  - Sara Cazzaniga – AFI – IQVIA
- 09.05 - 09.25      **Impact of AI in the healthcare and biomedical field: data of the future**
- Emanuele Lettieri – Politecnico di Milano
- 09.25 - 09.45      **AI and the digital ecosystem: the impact of technologies on healthcare professionals – the MIAL case**
- Teresa Castiello – Royal Society of Medicine
- 09.45 - 10.05      **The importance and methods of training neural networks in current systems and future risks**
- Mons. Renzo Pegoraro – Pontifical Academy for Life
- 10.05 - 10.25      **The use of AI in the pharmaceutical sector: the Partex experience**  
Jan Kirsten – Partex.AI
- 10.25 - 10.45      **Introduction of AI-enabled digital therapies in clinical practice: the INEST obesity project**
- Laura Lazzarotti – Theras Group
- 10.45 - 11.30      **Coffee break**
- 11.30 - 11.50      **Use of AI by specialist physicians and sustainable business models: the “Chat My Paper” case**
- Alberto Malva – MedQuestio
- 11.50 - 12.10      **Application of AI to drug dispensing: the Salus AI case**
- Lorenzo Fiore – Salus AI
- 12.10 - 12.30      **Synthetic data and rare diseases: AI supporting clinical research**  
Luca Bardoscia – Alexion Pharma
- 12.30 - 12.50      **The electronic package leaflet: impact on pharmaceutical manufacturers and distribution channels**
- Martina Perini – AFI – JSB Solutions
- 12.50 - 13.00      **Discussion and closing remarks**
- 13.00 - 14.30      **Networking Lunch in cooperation with**



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## SESSION VIII

### THE VOICE OF AI SERVING THE PATIENT: TOWARDS NEW DIGITAL ENGAGEMENT MODELS

#### Arco room

- Moderators:**
- Simona Aloe – AFI – Daiichi Sankyo Italia
  - Laura Patrucco – AFI – PRINEOS
- 09.00 - 09.15 **Introduction and context – The healthcare ecosystem in the age of Artificial Intelligence – Opening keynote**
- Fidelia Cascini – Istituto Superiore di Sanità, EU Health Data Space Committee, CCNCE AIFA
- 09.15 - 09.45 **Conversational AI in clinical practice and research: opportunities and limitations**
- Diana Ferro – SIIAM, Bambino Gesù Pediatric Hospital
  - Giulia Panizza – A.B.E.O. Liguria ODV ETS, FIAGOP ETS
- 09.45 - 10.00 **Health education in the digital era: self-medication and Artificial Intelligence**
- Michele Albero – President, Federchimica Assosalute
- 10.00 - 11.00 **Round Table – From theory to the patient: AI supporting patient engagement – case studies**
- Moderators:**
- Simona Aloe – AFI – Daiichi Sankyo Italia
  - Laura Patrucco – AFI – PRINEOS
- Speakers:**
- Alice Borghini – Age.na.s.
  - Valeria Glorioso – Confindustria Dispositivi Medici
  - Marco Greco – President, European Patient Forum
  - Marcella Marletta – Campus Bio-Medico University of Rome, Academy of Clinical and Health
  - Alessandro Stecco – UPOTELEMED, IRES Piemonte
- 11.00 - 11.30 **Coffee break**
- 11.30 - 11.50 **From information to action: AI supporting Real World Evidence (RWE)**
- Claudia Arosio – AFI – Roche
  - Daniela Gramaglia – AFI – Bayer
- 11.50 - 12.50 **Round Table – Data, technology and patients: building trust and value in the digital era. How to generate real-world evidence**
- Moderators:**
- Simona Aloe – AFI – Daiichi Sankyo Italia
  - Laura Patrucco – AFI – PRINEOS
  - Luca Cinquepalmi – Fondazione ENPAM
  - Laura Liguori – Portolano Cavallo Law Firm
  - Pietro Presti – SPCC – Sharing Progress in Cancer Care
  - Chiara Sgarbossa – Politecnico di Milano
- 12.50 - 13.00 **Discussion and closing remarks**
- 13.00 - 14.30 **Networking Lunch in cooperation with**  **Omnia Technologies**  
Life Sciences

#### Foyer Arco room

Area dedicated to the exhibition of posters submitted by Patient Associations. A representative from each Association will be present next to their poster to answer any questions from participants regarding the Association's initiatives.

14.00 - 14.45  
Tempio room

- Riccardo Zagaria – Egualia President  
**Keynote Lecture**  
Strategic autonomy, sustainability and access to treatment: the European off-patent pharmaceutical industry in the context of the new global balance of power

## SESSION IX

### FROM DIGITALIZATION TO ARTIFICIAL INTELLIGENCE

Tempio room

- 15.00 - 15.10      **Opening remarks**
- Alberto Bartolini – AFI – CIT
- 15.10 - 15.35      **Approach to a conscious digitalization process (GAMP 2nd edition, data integrity and associated data lifecycle)**
- Gian Paolo Baranzoni – AFI
  - Paola Martini – AFI – Takeda Manufacturing Italia
- 15.35 - 15.50      **Approach to the adoption of AI solutions, associated potential and possible applications**
- Paola Martini – AFI – Takeda Manufacturing Italia
- 15.50 - 16.05      **End-to-End AI Orchestration of Plasma Cold Storage Feeding Automated Cutting Machines**
- Roby Baldin – Takeda Manufacturing Italia
  - Daniela Ciccarone – Takeda Manufacturing Italia
- 16.05 - 16.30      **Adoption of an agile and innovative approach to computerized systems validation (GAMP 2nd edition, CSA)**
- Sandro de Caris – AFI – Studio de Caris
- 16.30 - 17.15      **Coffee break**
- 17.15 - 17.30      **Artificial Intelligence: Quality, Compliance and Risk – Public Infrastructure, Literacy and Governance of Probabilistic Systems**
- Valeria Lazzaroli – President, ENIA
- 17.30 - 18.00      **Cybersecurity: a must, not a nice-to-have**
- Gian Paolo Baranzoni – AFI
- 18.00 - 18.30      **Round Table on the topics discussed**
- Moderator:**
- Alberto Bartolini – AFI – CIT
- Speakers:**
- Roby Baldin – Takeda Manufacturing Italia (*to be confirmed*)
  - Gian Paolo Baranzoni – AFI
  - Daniela Ciccarone – Takeda Manufacturing Italia (*to be confirmed*)
  - Sandro De Caris – AFI – Studio de Caris
  - Marco Paolo Fulfaro – AIFA (*to be confirmed*)
  - Valeria Lazzaroli – Presidente ENIA (*to be confirmed*)
- 18.30 - 18.45      **Closing remarks**
- 20.00                **Symposium Gala Dinner at the Grand Hotel Rimini**  
*in cooperation with*

14.00 - 14.45  
Tempio room

- Riccardo Zagaria – Eguale President  
**Keynote Lecture**  
Strategic autonomy, sustainability and access to treatment: the European off-patent pharmaceutical industry in the context of the new global balance of power

## SESSION X

### REGULATORY AND TECHNOLOGICAL DEVELOPMENTS IN API PRODUCTION

Castello 1 room

- 15.00 - 15.10      **Opening remarks**
- Maurizio Battistini – AFI – EIPG
  - Piero Iamartino – AFI – EIPG
- 15.10 - 15.30      **Key aspects of European pharmaceutical legislation and implementation perspectives**
- Vincenzo Salvatore – bureau Plattner – University of Insubria
- 15.30 - 15.50      **Health sovereignty and API production: the role of the Critical Medicines Act and the Consolidated Pharmaceutical Legislation**
- Pierfrancesco Morosini – President, Federchimica Aschimfarma
- 15.50 - 16.10      **How Artificial Intelligence is Transforming API Site Operations**
- Davide Botta – Recordati
- 16.10 - 17.00      **Round Table with AIFA - From the national dimension to the global context: regulatory challenges and opportunities**
- Moderators:**
- Maurizio Battistini – AFI – EIPG
  - Piero Iamartino – AFI – EIPG
- Speakers:**
- Marcello Fumagalli – AFI – Chemical Pharmaceutical Generic Association
  - Stefania Mariani – Federchimica Assogastecnici
  - Pierfrancesco Morosini – President, Federchimica Aschimfarma
  - Luisa Stoppa – AIFA (*to be confirmed*)
  - Antonella Volpe – Federchimica Aschimfarma
- 17.00 - 17.30      **Discussion and closing remarks**
- 20.00                **Symposium Gala Dinner at the Grand Hotel Rimini**  
*in cooperation with*



14.00 - 14.45  
Tempio room

- Riccardo Zagaria – Egualia President  
**Keynote Lecture**  
Strategic autonomy, sustainability and access to treatment: the European off-patent pharmaceutical industry in the context of the new global balance of power

## SESSION VI – SECOND PART

AI SUPPORTING THE PHARMACEUTICAL SECTOR FROM DEVELOPMENT TO COMMERCIALIZATION OF MEDICINAL PRODUCTS – PHARMACEUTICAL SCIENCE, TECHNOLOGY AND REGULATION IN A PRESENT-DAY FUTURE WHERE HUMAN AND ARTIFICIAL INTELLIGENCE COLLABORATE FOR HEALTH

Castello 2 room

### FROM REGULATORY TO COMPLIANCE

- Moderators:**
- Sveva Sanzone – AFI – Biogen Italia
  - Francesco Scapin AFI – Fidia Farmaceutici
- 15.00 - 15.30      **Artificial Intelligence in the European regulatory strategy: the role of the AI Observatory**
- Marco Paolo Fulfaro – AIFA (*to be confirmed*)
- 15.30 - 16.00      **What's new in the new pharmaceutical legislation**
- Pietro Erba – DG SANTE – European Commission
- 16.00 - 16.30      **AI and the impact of its regulation on drug development**
- Elisa Stefanini – AFI – Portolano Cavallo
- 16.30 - 17.15      **Coffee break**
- 17.15 - 18.15      **Round Table – AI as a driver for the evolution of regulatory science**
- Moderators:**
- Sveva Sanzone – AFI – Biogen Italia
  - Francesco Scapin AFI – Fidia Farmaceutici
- Speakers:**
- Cinzia Berghella – AIFA (*to be confirmed*)
  - Marco Biagi – University of Parma
  - Marco Paolo Fulfaro – AIFA (*to be confirmed*)
  - Pietro Erba – DG SANTE – European Commission
  - Ilaria Maruti – AFI – Astrazeneca
  - Elisa Stefanini – AFI – Portolano Cavallo
- 18.15 - 18.30      **Discussion and closing remarks**
- 20.00                **Symposium Gala Dinner at the Grand Hotel Rimini**  
*in cooperation with*



14.00 - 14.45  
**Tempio room**

- Riccardo Zagaria – Eguale President  
**Keynote Lecture**  
**Strategic autonomy, sustainability and access to treatment: the European off-patent pharmaceutical industry in the context of the new global balance of power**

## **SESSION XI**

### **FOOD SUPPLEMENTS AND FOODS FOR SPECIAL MEDICAL PURPOSES: SCIENTIFIC, TECHNOLOGICAL AND REGULATORY ASPECTS**

#### **Arco room**

- 15.00 - 15.10      **Opening remarks**
- Bice Conti – AFI – SITELF – University of Pavia
  - Stefano Salmasso – Presidente CRS Italy Chapter – University of Padua
- Moderators:**
- Bice Conti – AFI – SITELF – University of Pavia
  - Stefano Salmasso – Presidente CRS Italy Chapter – University of Padua
- 15.10 - 15.30      **The food supplements market: trends and perspectives**
- Daniela Giuriati – President, Assointegratori
- 15.30 - 15.50      **Razionale farmacologico e clinico per l'impiego di integratori cardioprotettivi: evidenze e limiti**
- Arrigo Cicero – University of Bologna
- 15.50 - 16.15      **Quality aspects and the case of the disintegration test**
- Ruggero Bettini – University of Parma
- Moderators:**
- Carla Caramella – AFI – University of Pavia
  - Matteo Cerea – AFI – University of Milan
- 16.15 - 16.45      **Innovation in food supplements in Europe: opportunities and challenges between Novel Food and Pending Claims**
- Cinzia Menchise – Unione Italiana Food
  - Andrea Zanardi – AFI – Biofarmagroup
- 16.45 - 17.15      **Coffee break**
- 17.15 - 17.45      **Demarcation between foods for special medical purposes and food supplements**
- Roberto Copparoni – Ministry of Health
- 17.45 - 19.00      **Annual Meeting of CRS Italy Chapter**
- 20.00                **Symposium Gala Dinner at the Grand Hotel Rimini in cooperation with**

**HELIX**  
HEALTH COMMUNICATION HUB

## SESSION XII

### IMPACT OF AI ON PROFESSIONAL ROLES IN THE MEDICAL DEVICES SECTOR

Castello 2 room

- 09.30 - 09.40      **Welcome and introduction**
- Paola Minghetti – AFI Vice President – University of Milan
- Moderators:**
- Antonella Mamoli – AFI – IBSA Farmaceutici Italia
  - Marcella Marletta – Campus Bio-Medico University of Rome, Academy of Clinical and Health Research
- 09.40 - 10.05      **Artificial Intelligence in medical devices: clinical value, economic sustainability and reimbursement challenges**
- Valeria Glorioso – Confindustria Dispositivi Medici
- 10.05 - 10.30      **AI Act and MDR: regulatory impacts of Artificial Intelligence on medical devices**
- Alessandra Basilisco – Ministry of Health
- 10.30 - 10.50      **Not replacement but synergistic use: AI supporting expertise**
- Doriana Pantano – AFI – Schwabe Pharma Italia
- 10.50 - 11.30      **Coffee break**
- 11.30 - 11.50      **Use of AI in certification processes carried out by Notified Bodies**
- Daniele Bollati – IMQ
  - Sara Crocetti – Bureau Veritas
  - Paolo Dentis – Eurofins
  - Alessia Frabetti – KIWA CERMET
  - Alessandro Ricci – Istituto Superiore di Sanità
  - Armando Romaniello – Certiquality
- 11.50 - 12.30      **Discussion and closing remarks**
- 12.30 - 14.30      **Networking Lunch in cooperation with** 

## SESSION XIII

### ARTIFICIAL INTELLIGENCE: A NEW ALLY IN QUALITY CONTROL AND QUALITY ASSURANCE PROCESSES

#### Tempio room

- 09.00 - 09.10      **Welcome and introduction**
- Alessandro Regola – AFI Vice-President
- Moderators:**
- Marco Adami – AFI
  - Giovanni Boccardi – AFI
- 09.10 - 09.30      **Data, models and decisions: Artificial Intelligence supporting the laboratory – a snapshot**
- Fausto Gesualdi – AFI – F.I.S. Fabbrica Italiana Sintetici
- 09.30 - 09.50      **Generative and agentic Artificial Intelligence supporting R&D and Quality: application cases in a pharma company**
- Marinella Capuzzi – AFI – Italfarmaco
  - Stefano D'Ascoli – AFI – Eusoft
- 09.50 - 10.10      **Potential applications of Artificial Intelligence tools in the radiopharmaceutical manufacturing environment**
- Giuseppe Capasso – AFI – Itelpharma
  - Anna Tolomeo – AFI – Itelpharma
- 10.10 - 10.45      **A review of artificial intelligence applications in Quality Assurance**
- Markus Roemer – Comes Compliance Services
- 10.45 - 11.30      **Coffee break**
- Moderators:**
- Rita Brusa – AFI
  - Alessandro Regola – AFI Vice-President
- 11.30 - 11.50      **Validation of Artificial Intelligence applications in GMP environments**
- Pierluigi Agazzi – AFI – Adeodata
- 11.50 - 12.20      **Artificial Intelligence applications in deviation investigations and problem solving**
- Andrea Forgione – Bayer HealthCare Manufacturing
- 12.20 - 12.30      **Discussion and closing remarks**
- 12.30 - 14.30      **Networking Lunch in cooperation with** 

## SESSION XIV

### THE NEW ERA OF HTA: FROM REGULATION TO IMPACT ON THE ITALIAN HEALTHCARE SYSTEM

#### Castello 1 room

- 09.00 - 09.05 **Welcome**
- Paola Minghetti – AFI Vice-President – University of Milan
- 09.05 - 09.15 **Opening remarks**
- Simona Montilla – AIFA (*to be confirmed*)
  - Anna Ponzianelli – AFI
- Moderators:**
- Simona Montilla – AIFA (*to be confirmed*)
  - Anna Ponzianelli – AFI
- 09.15 - 09.35 **The HTA Regulation: the perspective of the Ministry of Health**
- Francesco Saverio Mennini – Università di Roma Tor Vergata – Ministry of Health
- 09.35 - 09.55 **The HTA Regulation: AIFA update**
- Rita Pacello – AIFA (*to be confirmed*)
- 09.55 - 10.15 **Price and Reimbursement Guidelines 3.0**
- Antonio La Greca – AIFA (*to be confirmed*)
- 10.15 - 10.35 **New AIFA innovation criteria: analysis from the HTA & Market Access Study Group**
- Giovanni Bellini – AFI – Eli Lilly Italia
  - Giulia Cattani – AFI – Johnson & Johnson
- 10.35 - 11.00 **Discussion and closing remarks (Part I)**
- 11.00 - 11.30 **Coffee break**
- 11.30 - 12.30 **Round Table – From the European HTA Regulation to implementation in Italy: first outcomes**
- Moderators:**
- Andrea Marcellusi – AFI – University of Milan
  - Ilaria Testa – AFI – Alnylam
- Speakers:**
- Massimo Di Maio – President, AIOM
  - Simona Montilla – AIFA (*awaiting authorization*)
  - Anna Ponzianelli – AFI
  - Paolo Sciattella – University of Rome Tor Vergata
  - Paolo Siviero – Farindustria
- 12.30 - 13.00 **Discussion and closing remarks**
- 13.00 - 14.30 **Networking Lunch in cooperation with** 

## SESSION START-UP

### START-UPS, AI AND FUTURE EDUCATION

#### Arco room

- 09.00 - 09.15      **Opening remarks: Because we need to rethink how we understand knowledge, not just how we educate ourselves**
- Lorenzo Cottini – AFI
  - Marica Nobile – Federchimica Assobiotec
- 09.15 - 09.35      **Innovating with (philosophical) foresight in the age of AI**
- Simona Chiodo – Politecnico di Milano
- 09.35 - 09.55      **New capabilities for AI in the healthcare and pharmaceutical sectors**
- Chiara Sgarbossa – Politecnico di Milano
- 09.55 - 10.25      **Startup Pitch Session**
- Moderators:**
- Marica Nobile – Federchimica Assobiotec
  - Maria Luisa Nollì – AFI – NCNbio
  - Paola Minghetti – AFI Vice-President – University of Milan
- Speakers:**
- Marco Giacosa – Salute360
  - Gianvito Grasso – InVirtuoLabs
  - Walter Marchi – aixelerate
- 10.25 - 10.45      **Discussion and closing remarks**
- 10.45 - 11.30      **Coffee break**

## YOUNG TALENTS CONTEST SESSION

### Arco room

- 11.30 - 11.40      **Opening remarks**
- Paola Minghetti – AFI Vice-President – University of Milan
  - Francesca Selmin – University of Milan
- 11.40 - 12.20      **From idea to business: innovation in the healthcare industry**  
Maurizio Battistini – AFI – EIPG  
Maria Luisa Nolli – AFI – NCNbio
- 12.20 - 12.40      **Project presentation: “SpinoSave®: A low-risk autologous TEP as a new treatment for acute spinal cord injury (SCI)”**
- Zoe Giorgi – Regenera SA
  - Ettore Limido – Regenera SA
- 12.40 - 13.00      **Project presentation: “InFem: integrated drug delivery system and digital support for the personalised management of recurrent vaginal infections”**
- Gianmarco Di Vina – University of Pisa
  - Valentina Paganini – University of Pisa
- 13.00 - 13.20      **Project presentation: “Mag-Pop”**
- Emanuela La Polla – University of Milan
  - Martina Managò – University of Milan
  - Paola Signori – University of Milan
- 13.20 - 13.30      **Award ceremony**
- 13.30 - 14.30      **Networking Lunch in cooperation with** 

## THURSDAY, 11 JUNE – GALA DINNER AT THE GRAND HOTEL RIMINI

### Luigi Cavenaghi Award

The award, established by Dr. Maria Luisa Nolli in memory of Dr. Luigi Cavenaghi for young researchers, will be granted to the best poster.

## POSTER

The **65th AFI Symposium** includes the presentation of posters featuring original work on topics covering the entire pharmaceutical value chain, from chemically synthesized drugs to biotech products and advanced therapy medicinal products. Topics of interest include concept development, research and development, innovative solutions in quality control and quality assurance, manufacturing, intellectual property protection, clinical research, regulatory aspects, and therapeutic use. A dedicated session will be organized to allow Symposium participants to discuss the posters directly with their authors. The most interesting and innovative poster, as evaluated by a panel of experts appointed by AFI, will be awarded a prize of €1,000, established by Dr. Maria Luisa Nolli, co-founder of NCNbio, in memory of Dr. Luigi Cavenaghi, former President of the Association. Certificates recognizing outstanding scientific contribution will also be awarded to the second- and third-ranked posters. An additional recognition will be reserved for young authors (undergraduate, postgraduate, or PhD students).

**The award ceremony will take place on the evening of Thursday, 11 June, at the Grand Hotel Rimini, during the Gala Dinner.**

The poster submission form and the abstract template must be submitted **no later than 15 May 2026**, this being a strict and non-extendable deadline, via the online form available at the following link:

<https://simposio.afiscientifica.it/poster/>

For further information, please contact **il Dott. Giovanni Boccardi**  
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e-mail: [segreteria@afiscientifica.it](mailto:segreteria@afiscientifica.it)

The Poster Committee will review all submitted abstracts, verify that the work has not been previously published, and decide whether to accept them for presentation at the Symposium. Acceptance will be communicated to the corresponding author, who will be invited to register for the Symposium together with any co-authors. **Registration is free of charge and mandatory** for organizational purposes, and grants access to the exhibition area, participation in Wednesday morning workshops, the Start-up Session, and the Young Talents Contest Session on **Friday, 12 June**.

**[CLICK HERE for online registration](#)**

**Access to the Scientific Sessions is subject to a fee** and requires registration for the Symposium.

**[CLICK HERE for paid online registration](#)**

Posters accepted for presentation will remain on display in the foyer of the Arch Hall throughout the entire duration of the Symposium. Abstracts of the accepted posters will be published in the "Symposium Proceedings", which will be available online on the Symposium website.

On **Thursday, 11 June**, from 12:30 to 14:30, one of the authors must be present next to their poster to answer any questions from participants regarding the presented work.

### RECIPHARM ITALIA AWARD 2026

Recipharm Italia, a leading CDMO company, is launching a new initiative in collaboration with Italian universities aimed at awarding the best master's thesis on the topic: **Formulations for Pediatric Use**.

The award is intended to strengthen the connection between academia and industry, offering an opportunity to young graduates completing their academic journey.

The two best theses, selected by a panel of experts from both industry and academia, will receive a monetary prize and a certificate of merit.

**The award ceremony will take place during the Gala Dinner on 11 June 2026 at the Grand Hotel Rimini, providing a special occasion to celebrate achievements and foster networking among key stakeholders in the sector.**

For further information, please contact the AFI Secretariat by email at: [segreteria@afiscientifica.it](mailto:segreteria@afiscientifica.it)

Participants are required to submit their master's thesis. In the case of graduating students, non-final versions of the thesis will also be accepted.

**The two best submissions will receive a prize of €500 each, which will be awarded during the AFI Symposium.**



#### TIMELINE

- **By 27 April 2026**, submission of theses (in Italian) to the AFI Secretariat via email at [segreteria@afiscientifica.it](mailto:segreteria@afiscientifica.it)
- **By 29 May 2026**, evaluation of submissions by the Selection Committee
- **11 June 2026**, award ceremony at the Grand Hotel Rimini during the Gala Dinner; Recipharm Italia will be pleased to host the winners

## GENERAL INFORMATION

### SCIENTIFIC SECRETARIAT

#### AFI

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 Office Hours: 13:30 – 17:30, Monday to Friday  
[www.afiscientifica.it](http://www.afiscientifica.it)

### ORGANIZING SECRETARIAT

#### NEW AURAMEETING S.r.l.

Via Rocca D'Anfo, 7 - 20161 MILAN (Italy)  
 Phone +39 02 66203390  
 Fax +39 02 45486457  
[eventi@newaurameeting.it](mailto:eventi@newaurameeting.it)  
 Office Hours: 09:00 – 17:30, Monday to Friday  
[www.newaurameeting.it](http://www.newaurameeting.it)

## PARTICIPATION FEES

	Until 13 May		After 13 May	
	VAT EXCLUDED	VAT 22% INCLUDED	VAT EXCLUDED	VAT 22% INCLUDED
<b>AFI, AFTI, CRS, SITELF Members</b>	€ 900,00	€ 1.098,00	€ 1.050,00	€ 1.281,00
<b>Non Members</b>	€ 1.200,00	€ 1.464,00	€ 1.200,00	€ 1.464,00
<b>Public Institutions, Universities, IRCCSs, Hospitals, Ministries</b> (networking lunches, WHITE & BLUE Beach Party and Gala Dinner not included)	€ 400,00	€ 488,00	€ 450,00	€ 549,00
<b>Daily</b> (valid for registration to one of the three days of the Symposium; WHITE & BLUE Beach Party and Gala Dinner not included)	€ 600,00	€ 732,00	€ 650,00	€ 793,00
<b>Daily – Public Institutions, Universities, IRCCSs, Hospitals, Ministries</b> (valid for registration to one of the three days of the Symposium; networking lunches, WHITE & BLUE Beach Party and Gala Dinner not included)	€ 300,00	€ 366,00	€ 300,00	€ 366,00

### REGISTRATION FEE INCLUDES

- Access to Scientific Sessions and exhibition area
- Congress proceedings and materials
- Three networking lunches (not included for Public Institutions)
- Four coffee breaks
- WHITE & BLUE Beach Party – 10 June (not included in daily or Public Institution fees)
- Gala Dinner – 11 June (not included in daily or Public Institution fees)

**Any CANCELLATIONS received in writing by 17 May 2026 will be eligible for a 50% refund. No refunds will be granted after this date.**

For online registration, to be completed by 17 May 2026

**[CLICK HERE](#)**

For further information, please visit the website <http://simposio.afiscientifica.it/>

### HOTEL BOOKING

New Aurameeting offers a selection of hotels at **special rates during the Symposium**. The booking includes a **shuttle service**, at the start and end of the daily sessions, from the selected hotel to the Palacongressi in Rimini and back.

**[Download the hotel booking form](#)**

to be submitted by 17 May 2026 to:

[eventi@newaurameeting.it](mailto:eventi@newaurameeting.it)

# TIMETABLE

	Wednesday, June 10 14.00 - 18.45	Thursday, June 11 09.00 - 13.30	Thursday, June 11 14.00 - 19.00	Friday, June 12 09.00 - 13.30
TEMPIO ROOM	<p><b>14.00 – 15.00</b> <b>BENVENUTO E APERTURA DEL SIMPOSIO</b></p> <p><b>Keynote Lecture</b> The Healthcare Industry in the Age of Artificial Intelligence</p>	<p><b>09.00 – 13.20</b> <b>SESSION V PRODUCTION</b> The role of AI and new technologies in supporting pharmaceutical manufacturing</p>	<p><b>14.00 – 14.45</b> <b>Keynote Lecture</b> Strategic autonomy, sustainability and access to treatment: the European off-patent pharmaceutical industry in the context of the new global balance of power</p>	<p><b>09.00 – 13.00</b> <b>SESSION XIII QUALITY</b> Artificial Intelligence: a new ally in Quality Control and Quality Assurance processes</p>
	<p><b>15.15 – 18.45</b> <b>SESSION II BIOTECH &amp; ADVANCED THERAPIES</b> The digital world: challenges and opportunities for biotech drugs and advanced therapy medicinal products</p>		<p><b>15.00 – 18.45</b> <b>SESSION IX INNOVATION</b> From digitalization to Artificial Intelligence</p>	
CASTELLO 1 ROOM	<p><b>15.15 – 18.30</b> <b>SESSION I RICERCA CLINICA</b> AI, RWE and new regulations: simplifying and innovating to enhance the competitiveness of Italian clinical research</p>	<p><b>09.00 – 13.00</b> <b>SESSION VII DIGITAL HEALTH</b> The impact of AI on the healthcare sector: how technologies are transforming the industry</p>	<p><b>15.00 – 17.30</b> <b>SESSION X RAW MATERIALS</b> Regulatory and technological developments in API production</p>	<p><b>09.00 – 13.00</b> <b>SESSION XIV HTA &amp; MARKET ACCESS</b> The new era of HTA: from regulation to impact within the Italian healthcare system</p>
CASTELLO 2 ROOM	<p><b>15.15 – 18.30</b> <b>SESSION III PHARMACOVIGILANCE</b> The evolution of important safety communications</p>	<p><b>09.00 – 13.00</b> <b>SESSION VI REGULATORY (PART I)</b> AI supporting the pharmaceutical sector from development to commercialization of medicinal products – pharmaceutical science, technology and regulation in a present-day future where human intelligence and artificial intelligence collaborate for health</p>	<p><b>15.00 – 18.30</b> <b>SESSION VI REGULATORY (PART II)</b> AI supporting the pharmaceutical sector from development to commercialization of medicinal products – pharmaceutical science, technology and regulation in a present-day future where human intelligence and artificial intelligence collaborate for health</p>	<p><b>09.30 – 12.30</b> <b>SESSION XII MEDICAL DEVICES</b> Impact of AI on professional roles in the Medical Devices sector</p>
ARCO ROOM	<p><b>15.15 – 18.15</b> <b>SESSION IV SUPPLY CHAIN</b> Traceability; GDP and AI application in the pARmaceutical supply chain</p>	<p><b>09.00 – 13.00</b> <b>SESSION VIII PATIENT VOICE &amp; VALUE (PVV)</b> The voice of AI serving the patient: towards new digital engagement models</p>	<p><b>15.00 – 19.00</b> <b>SESSION XI PHARMACEUTICAL SCIENCES CRS/SITELF</b> Food supplements and foods for special medical purposes: scientific, technological and regulatory aspects</p>	<p><b>09.00 – 10.45</b> <b>START-UP SESSION</b> Start-ups, AI and future education</p>
				<p><b>11.30 – 13.30</b> <b>YOUNG TALENTS CONTEST SESSION</b></p>
FOYER ARCO ROOM		<p><b>12.30 – 14.30</b> <b>POSTER SESSION</b></p>		



Associazione Farmaceutici Industria  
Società Scientifica

Scientific Secretariat  
AFI

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Organizing Secretariat

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RIMINI 10-11-12 JUNE 2026



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