SIMeF
Società Italiana di Medicina Farmaceutica
Italian Society of Pharmaceutical Medicine

Ricerca Clinica & Medical Affairs (RICMA)

ATTIVITA' 2023
&
LISTA MEMBRI

TC ogni PRIMO giovedì del mese

RICMA	
Alessandra Aloe – Merck	Med Aff
Alessandro D'Apice - Janssen	Med Aff
Betty Polikar -	Clin Ops
Chiara Povesi – Bayer	Clin Ops
Chiara Gussetti – GSK	Clin Ops
Cinzia Dorigo - Alexion	Clin Ops
Corrado Confalonieri – H.PR	Comitato Etico
Domenico Criscuolo - SIMeF	Esp Med Aff
Elisabetta Riva - HSR	Comitato Etico
Francesca Vaccari - Chiesi	Clin Ops
Francesco Butti – Boeringer I.	Clin Ops
Giuseppe Assogna - SIMeF	Esp Med Aff
Ilaria Maruti - Astrazeneca	Clin Ops
Livio Di Lecce – Advanz Pharma	Med Aff
Loredana Bergamini -	Comitato Etico
Loretta Aureli - Bracco	ClinOps
Luciano Fuccella - SIMeF	Esp Med Aff
Mariangela Amoroso - Sanofi	Med Aff
Paola Fattore - MSD	Clin Ops
Paola Trogu - Astrazeneca	Clin Ops
Ramona Cavallini - MSD	Clin Ops
Silvia Michelagnoli- Sanofi	Clin Ops
Stefano Alvergna -	Med Aff
Valentina Manno - Novonordisk	Clin Ops
Veronica Crippa - Novartis	Clin Ops
Roberto Vallalta - GSK	Clin Ops
Tiziana Musacchio – AbbVie	Med Aff

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RICMA	
Alessia Gallastroni - Bayer	MSL
Stefania Grieco - MSD	MSL
Mattia Pagnani - Sanofi	MSL
Paola Ferrario - Sanofi	Med Info
Milena Sartori (Roche)	Med Info
Anika Filandri (Chiesi)	Med Info
Paola Rapetti (Pfizer)	Med Info
Roberto La Ferla (Gilead)	Med Info

CONSUNTIVO ATTIVITA' 2023

16.01.2023

CORSO QA

SECONDA EDIZIONE

17.03.2023

TAVOLA ROTONDA SUI NUOVI DECRETI

20.05.2023

CLINICAL TRIAL DAY IN PIAZZA CON AFI, GIDM, FADOI

CORSO DIGITAL

FOCUS ALFABETIZZAZIONE, PIATTAFORME, TECNOLOGIE, TELEMEDICINA (TBD)

COMMENTI EMA SINGLE ARM

WORKSHOP CE

APPENA DEFINITI I 40 CE DA DECRETO

WEBINAR DCT

VIDEO 2024

FOCUS MSL:

SURVEY

RIPRESA CORSO 2024

SOTTOGRUPPI 2023

CORSO QA

Paola T,

Betty, Eva, Annamaria, Roberta, Maurizio, Valentine, Anna, Oriana, Celeste

TAVOLA ROTONDA

Paola T

Paola F

Ilaria

Chiara

Corrado

Elisabetta

Roberto

Ramona

Domenico

Adriana

CLINICAL TRIAL DAY

PAOLA

ILARIA

MG BESSE

AFI, FADOI, GIDM, FI

CORSO DIGITAL

ALESSANDRA,

ILARIA, EMILIA, CORRADO, MARIANGELA, SALVATORE (SIMEF GIOVANI), LISA (PV)

WORKSHOP CT

PAOLA T

PAOLA F

ILARIA

#ADCO

WEBINAR DCT

ILARIA

SILVIA

CORRADO

COLLAMATI?

MSD?

FOCUS MSL

Mariangela, Francesco, Alessandra, Tiziana, Chiara G, M. Ibba, T. Parrino + Livio, Alessandro, Loredana

GIDM
Coordinatori di Ricerca Clinica
Gruppo Italiano Data Manager

SIMeF
Società Italiana di Medicina Farmaceutica
Italian Society of Pharmaceutical Medicine

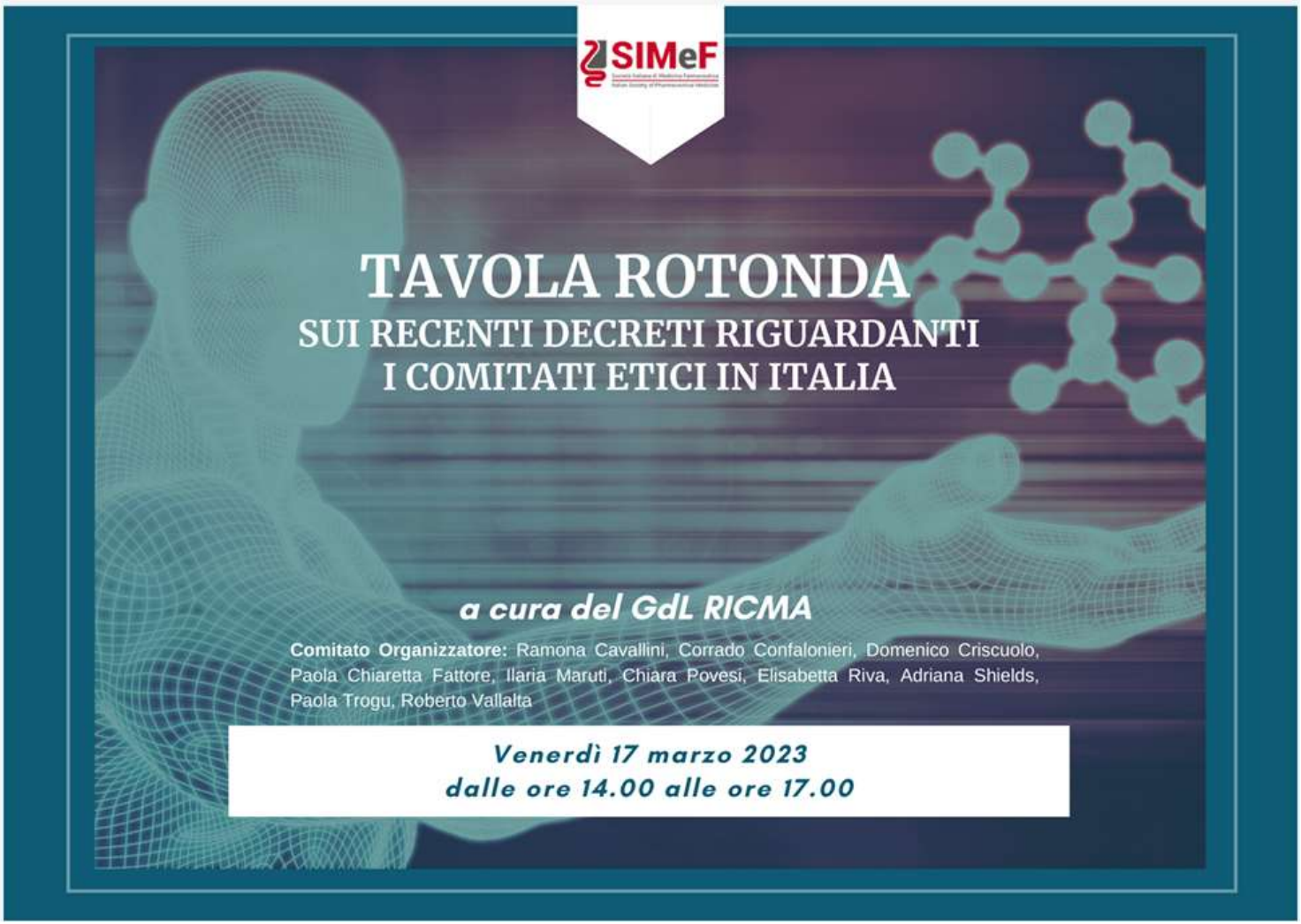
50 iscritti/
50 posti totali

CORSO PER QUALITY ASSURANCE E AUDITOR

DAL **16 GENNAIO** AL **23 MARZO 2023** TUTTI I

LUNEDÌ
GIOVEDÌ

DALLE ORE 14.00 ALLE ORE 17.00

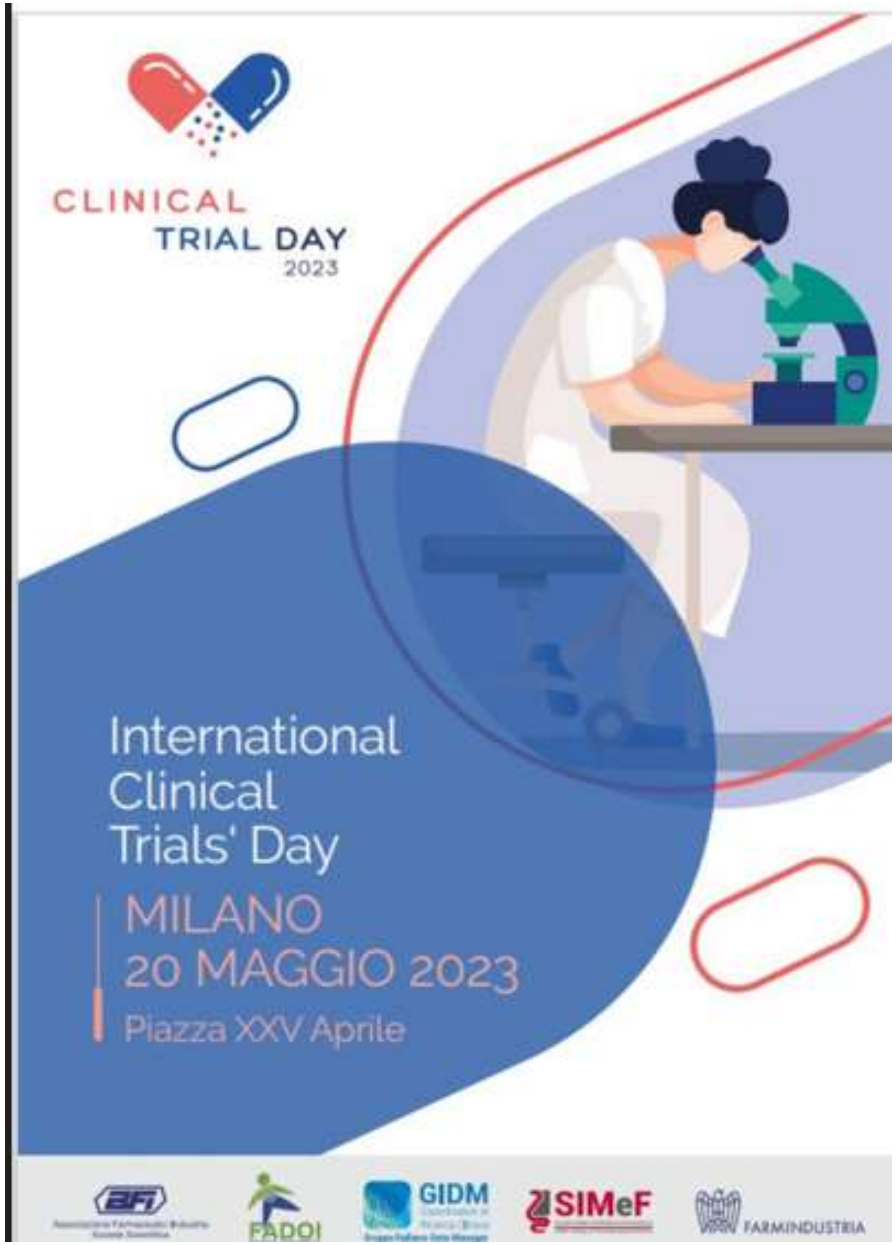


> 1000 iscritti

Il giornale della SIMeF

N°2/2023

Società Italiana di Medicina Farmaceutica
Italian Society of Pharmaceutical Medicine


CLINICAL
TRIAL DAY
2023
International
Clinical
Trials' Day
MILANO
20 MAGGIO 2023
Piazza XXV Aprile
FADOI
GIDM
SIMeF
FARMINDUSTRIA

COMMENTI PER CONSULTAZIONE APERTA EMA

Single-arm trials as pivotal evidence for the authorisation of medicines in the EU

EMA has opened a public consultation on a reflection paper that discusses key concepts for single-arm clinical trials that are submitted as pivotal evidence in support of marketing authorisation applications for medicines in the European Union (EU). This is the first guidance document by an international medicine regulator articulating the considerations and challenges associated with this type of clinical trials. Stakeholders are invited to send their comments via an online form by midnight (CET) on 30 September 2023.

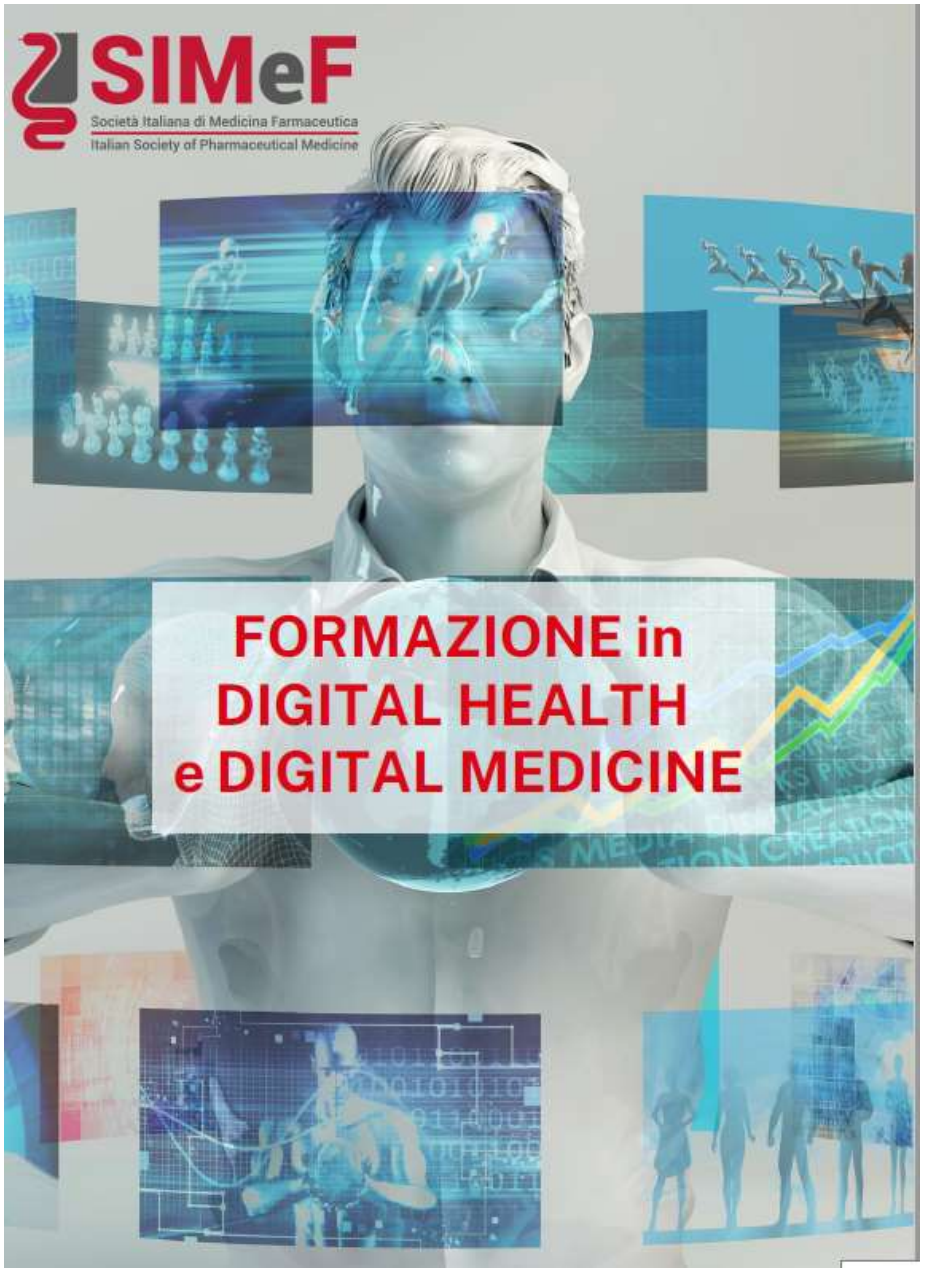
Randomised clinical trials (RCTs) in which a new treatment is compared against a placebo or an existing standard of care are widely considered as the gold standard for generating evidence needed by regulatory authorities to assess the efficacy and safety of a new medicine. In RCTs, patients are randomly assigned to either the active treatment or the control arm. Usually, large numbers of patients are included for these trials to generate robust data on the efficacy of a treatment.

In certain areas such as rare diseases, including rare cancers, where target populations of new medicines are often very small, a proportion of marketing authorisation applications are submitted to EMA with clinical data from single-arm trials as pivotal evidence. Because there is no randomised comparator in a single-arm trial, all patients in the trial receive the experimental treatment and only the outcomes under the experimental treatment can be observed.

The reflection paper outlines considerations on single-arm trials that are submitted as pivotal evidence to demonstrate efficacy in a marketing authorisation application. It aims to stimulate the scientific discussion around key concepts and challenges associated with single-arm trials and to improve their design and conduct.

The reflection paper has been adopted by EMA's human medicines committee (CHP) with contributions from the Committee for Advanced Therapies (CAT), the Methodology Working Party (MWP) and the Oncology Working Party (ONCWP).

Following the public consultation, comments from stakeholders will be analysed and considered in the final document that is planned to be published in 2024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DIGITAL HEALTH
e DIGITAL MEDICINE