

Giovanni Monteleone

QUALIFICHE PROFESSIONALI

- 7/2/1991. Laurea in Medicina e Chirurgia (massimo dei voti e lode), Università di Reggio Calabria, Catanzaro;
- 18/12/1996. Specializzazione in Gastroenterologia ed Endoscopia Digestiva, Università di Reggio Calabria, Catanzaro
- 9/4/2002. Titolo di Dottorato in Immunologia Sperimentale, Università Magna Graecia di Catanzaro, Catanzaro.

INDIRIZZI

- Cattedra di Gastroenterologia
Dipartimento di Medicina dei Sistemi
Università Tor Vergata di Roma,
Via Montpellier, 1
00133 ROMA
- UOC Gastroenterologia
Policlinico Tor Vergata
Viale Oxford 81
00133 Roma

POSIZIONE ATTUALE

Professore Ordinario in Gastroenterologia, Cattedra di Gastroenterologia, Dipartimento di Medicina dei Sistemi, Università degli Studi Tor Vergata di Roma, (settore scientifico-disciplinare MEDS-10/A, ex MED/12).

Direttore Unità Operativa Complessa di Gastroenterologia, Policlinico Universitario Tor Vergata, Roma, dal 2015

Direttore ff Dipartimento di Scienze Mediche, Policlinico Universitario Tor Vergata, Roma, dal 2024.

Direttore ff Unità Operativa Complessa di Cardiologia, Policlinico Universitario Tor Vergata, Roma, da marzo 2025

Direttore Scientifico Centro Sperimentale di fase 1 Policlinico Universitario Tor Vergata, Roma dal 2018.

Vice-Presidente, Società Italiana di Gastroenterologia ed endoscopia Digestiva, dal 2023.

SERVIZI PRESTATI E POSIZIONI OCCUPATE

Periodo 1/10/2003 - 30/09/2006

Ricercatore non confermato in Gastroenterologia, Cattedra di Gastroenterologia, Dipartimento di Medicina Interna, Università degli Studi Tor Vergata di Roma, (settore scientifico-disciplinare MED/12).

Periodo 1/10/2006 – 31/10/2007

Ricercatore confermato in Gastroenterologia, Cattedra di Gastroenterologia, Dipartimento di Medicina Interna, Università degli Studi Tor Vergata di Roma,

(settore scientifico-disciplinare MED/12).

Periodo 1/11/2007 – al 31/10/2014

Professore Associato in Gastroenterologia, Cattedra di Gastroenterologia, Dipartimento di Medicina dei Sistemi, Università degli Studi Tor Vergata di Roma,
(settore scientifico-disciplinare MED/12).

Periodo 1/11/2014 – ad oggi

Professore Ordinario in Gastroenterologia, Cattedra di Gastroenterologia, Dipartimento di Medicina dei Sistemi, Università degli Studi Tor Vergata di Roma,
(settore scientifico-disciplinare MED/12).

Periodo 1/11/2015 – 19/03/2018

Direttore UOC ff Gastroenterologia ed Endoscopia Digestiva, Policlinico Universitario Tor Vergata, Roma

Periodo 20/03/2018 – ad oggi

Direttore UOC di Gastroenterologia, Policlinico Universitario Tor Vergata, Roma

Periodo 31/10/2019 – gennaio 2026

Direttore Scuola di Specializzazione in Malattie dell'Apparato Digerente Università degli Studi Tor Vergata di Roma.

ATTIVITA' EDITORIALE E RESPONSABILITA' SCIENTIFICHE

Membro Editoriale della rivista Clinical Science dal 2008

Membro Editoriale della Rivista World Journal of Gastroenterology dal 2004

Membro Editoriale della Rivista GUT dal 2009

Membro Editoriale della Rivista Journal of Crohn's disease and colitis dal 2007

Membro Editoriale della Rivista The World Journal of Gastrointestinal Pharmacology and Therapeutics dal 2012

Membro Editoriale: Journal of Liver and Clinical Research dal 2014

Membro Editoriale: Journal of Traslational Internal Medicine dal 2014

Membro Editoriale della Rivista Digestive Liver and Disease dal 2008 al 2010

Membro Editoriale della Rivista Cancers dal 2021

Editore Associato della Rivista Frontiers Immunology, sezione Cancer Immunity and Immunotherapy dal 2022

Membro Editoriale della Rivista Oncology Research dal 2023

Reviewer delle seguenti riviste: The New England Journal of Medicine, Nature, Nature Medicine, Nature Immunology, Nature Review Immunology, Nature Gastroenterology and Hepatology, Nature Reviews Disease Primers, Nature Communications, Nature Genetics, Science Transl Medicine, Lancet Gastroenterology and Hepatology, Lancet Respiratory Medicine, Gastroenterology, Gut, Cell and Mol Gastroenterology and Hepatology, American Journal of Gastroenterology, The Journal of Clinical Investigation, The Journal of Immunology, Neoplasia, Cell Death Dis, International Immunology, Advance Science, Cell Molecular Immunology, Mucosal Immunology, Scandinavian Journal of Gastroenterology, • Clinical Experimental Immunology, European Journal of Immunology, Digestive and Liver Disease, •Inflammatory Bowel Diseases, European Journal of Gastroenterology, Digestive Diseases and Science, Oncogene, J Exp Med, Journal of Pediatric Gastroenterology and Nutrition, World Journal of Gastroenterology, American Journal of Pathology, Journal of Pathology, Disease Colon & Rectum, Apoptosis, Clin Science, Eur Journal of Cancer, Journal of Crohn's disease and colitis, Plos One, Ebiomedicine, Cancers, EClinical Medicine, Biodrugs, Frontiers in Pharmacology, Frontiers in Immunology.

Revisore Progetti PRIN

Ruoli in Società Scientifiche dal 2003 ad oggi:

Membro Societario: Società Italiana di Gastroenterologia.

Membro Societario della Società "Mucosal Immunology"

Membro Societario del gruppo Scientifico IG-IBD

Responsabile del board Editoriale per il sito SIGE

Componente della pregressa Commissione Scientifica SIGE

Componente del Comitato Scientifico IG-IBD (2014-2015)

Componente Comitato Coordinatore IG-IBD (2011-2012)

ORGANIZZAZIONE DI CONVEGNI ACCREDITATI

- Giugno 2003: Corso IBD. Hot topics nel trattamento delle Malattie Infiammatorie Croniche Intestinali.
- Dicembre 2003: IRG – INFLAMMATION RESEARCH IN GASTROENTEROLOGY. Celiac Disease: pathogenesis and future therapies
- Luglio 2004: IRG – INFLAMMATION RESEARCH IN GASTROENTEROLOGY: Intestinal Tolerance: failure and success.
- Dicembre 2010: Forum Nazionale delle Malattie Infiammatorie Croniche Intestinali: dal bambino all' adulto.
- Marzo 2018: IRG – INFLAMMATION RESEARCH IN GASTROENTEROLOGY. An interactive discussion.

- Novembre 2018: IRG – INFLAMMATION RESEARCH IN GASTROENTEROLOGY.
An interactive discussion.
- Luglio 2019: IRG – INFLAMMATION RESEARCH IN GASTROENTEROLOGY.
An interactive discussion.
- Settembre 2022: Advanced Research in intestinal inflammation and cancer

ATTIVITA' DIDATTICA

- Insegnamento nell'ambito del corso di Laurea in Medicina e Chirurgia, Università degli Studi Tor Vergata di Roma.
- Coordinamento dell'elaborazione di tesi di Laurea per gli studenti del corso di Laurea in Medicina e Chirurgia, Università degli Studi Tor Vergata di Roma.
- Insegnamento nell'ambito dell'Attività Didattica Opzionale (ADO), dei Corsi di "Immunologia clinica ed immunopatologia delle malattie digestive" e "Malattie infiammatorie intestinali", presso la Cattedra di Gastroenterologia, Università degli Studi Tor Vergata di Roma.
- Insegnamento nell'ambito della Scuola di Specializzazione in Malattie dell'Apparato Digerente, presso la Cattedra di Gastroenterologia, Università degli Studi Tor Vergata di Roma
- Insegnamento nell'ambito del corso di Diploma di Laurea Specialistica in Biotecnologie Mediche, Scienze della Nutrizione Umana, Università degli Studi Tor Vergata di Roma.
- Insegnamento nell'ambito del corso di Laurea Infermieristica, Università degli Studi Tor Vergata di Roma.
- Insegnamento nell'ambito della Scuola di Specializzazione in Malattie dell'Apparato Cardiovascolare, Psichiatria, Scienza dell'Alimentazione, e Medicina Nucleare, Università degli Studi Tor Vergata di Roma.
- Insegnamento nell'ambito del corso di Dottorato in Fisiopatologia Sperimentale, Dipartimento di Medicina dei Sistemi, Università degli Studi Tor Vergata di Roma.

ATTIVITA' CLINICA

L'attività clinica è stata svolta presso la Cattedra di Gastroenterologia, Dipartimento di Medicina Sperimentale e Clinica, Facoltà di Medicina e Chirurgia di Catanzaro, Università di Reggio Calabria, in qualità di medico interno (1991-1992), specializzando (1992-1996) e specialista in Gastroenterologia ed Endoscopia Digestiva (1996-1999). Dal 2002 a tutt'oggi, l'attività clinico-assistenziale è stata svolta presso la Cattedra di Gastroenterologia e Reparto di Medicina Interna dell'Università Tor Vergata, Policlinico Tor Vergata, di Roma.

L'attività clinico-assistenziale è consistita in:

a. Attività Ambulatoriale

Svolgimento in prima persona di attività ambulatoriale di Gastroenterologia generale ed ambulatori specialistici di pazienti con malattie infiammatorie croniche intestinali e malattia celiaca.

b. Attività di Reparto (Policlinico Tor Vergata)

1. Coordinamento e supervisione dell'attività di ricovero in regime di Day Hospital presso la Cattedra di Gastroenterologia, Dipartimento di Medicina Interna.

2. Coordinamento e supervisione del servizio di fisiopatologia clinica presso la Cattedra di Gastroenterologia, Dipartimento di Medicina Interna.

3. Responsabile dell'attività di Reparto presso la Cattedra di Gastroenterologia, Dipartimento di Medicina Interna.

4. Attività di Guardie Interdipartimentali diurne, festive e notturne, previste nell'ambito dell'attività del Dipartimento di Medicina Interna.

c. Coordinatore e responsabile dello studio di fase 1 condotto presso il Policlinico Tor Vergata ed avente come obiettivo la valutazione della sicurezza, tossicità e della risposta clinica del farmaco oligonucleotide antisenso contro Smad7 in pazienti con malattia di Crohn.

d. Coordinatore e responsabile dello studio di fase 2 multicentrico, avente come obiettivo la valutazione dell'efficacia clinica del farmaco oligonucleotide antisenso contro Smad7 in pazienti con malattia di Crohn.

e. Coordinatore e responsabile dello studio clinico pilota "VALUTAZIONE DELL'EFFICACIA DI UNA PREPARAZIONE COMMERCIALE A BASE DI LACTOBACILLUS CASEI DG NELLA RIDUZIONE DELLA SINTOMATOLOGIA DOLOROSA ASSOCIATA ALLA SINDROME DELL'INTESTINO IRRITABILE".

f. Coordinatore e responsabile dello studio di fase 1 multicentrico avente come obiettivo la valutazione della sicurezza, tossicità e della risposta clinica del farmaco Niclosamide in pazienti con Rettocolite Ulcerosa distale.

f. Responsabile dei seguenti studi sperimentali:

1. Studio di fase 2: Multicenter, Randomized, Double-blind, Parallel-group, Placebo-controlled Trial of IBD98-M Delayed-release Capsules to Induce Remission in Patients with Active, Mild to Moderate Ulcerative Colitis.
2. Studio di fase 2/3: studio combinato di induzione e mantenimento, in doppio cieco, randomizzato, controllato verso placebo volto a valutare la sicurezza e l'efficacia di GS-5745 nei soggetti con colite ulcerosa da moderatamente a gravemente attiva.
3. Studio di fase 2: studio, multicentrico, randomizzato, controllato versus placebo per valutare l'efficacia e la sicurezza di GED-0507-34-Levo (GED0507) per il trattamento di soggetti affetti da colite ulcerosa in fase attiva.
4. Studio di fase 2: studio multicentrico, in aperto e con periodo di estensione, volto a valutare il miglioramento endoscopico e le variazioni dei biomarcatori sierici ed intestinali in pazienti affetti di MDC da moderatamente a gravemente attivo trattati con RPC1063 per via orale

come terapia di induzione.

5. Studio sulla sicurezza a lungo termine di Entyvio (vedolizumab): uno studio di coorte, prospettico, osservazionale e internazionale che compara vedolizumab ad altri agenti biologici in pazienti affetti da colite ulcerosa o malattia di Crohn.
6. Efficacia di ABT-494 come terapia di induzione e mantenimento in soggetti con CU in fase attiva di grado da moderato a severo UC.
7. Ruolo della microflora intestinale e del sistema immunitario nella patogenesi delle Malattie Infiammatorie Croniche Intestinali e della Sindrome dell'Intestino Irritabile: studio trasversale multicentrico.
8. Fattori predittivi di cambio del fenotipo delle lesioni nella malattia di Crohn.
9. Studio di fase 2, randomizzato, controllato con placebo, trattamento di soggetti con colite ulcerosa attiva con Apremilast.
10. Studio di fase 2, in aperto per valutare gli effetti farmacodinamici e clinici di Mongersen (GED-0301) in soggetti con Morbo di Crohn in fase attiva
11. Studio multicentrico di fase 3, randomizzato, in doppio cieco, controllato con placebo per valutare l'efficacia e la sicurezza di mongersen (Ged-0301) per il trattamento di soggetti con malattia di Crohn in fase attiva.
12. Studio di estensione di fase 3 con trattamento attivo a lungo termine di mongersen (GED-0301) in soggetti con morbo di Crohn.
13. Sperimentazione multicentrica di estensione in aperto (OLE) di Fase III per valutare la sicurezza e l'efficacia a lungo termine di ABT-494 in soggetti affetti da colite ulcerosa.
14. Studi combinati di fase 2b/3, in doppio cieco, randomizzati, controllati con placebo, per la valutazione dell'efficacia e della sicurezza di Filgotinib nell'induzione e nel mantenimento della remissione in soggetti con colite ulcerosa attiva di grado da moderato a severo.
15. Studio di fase 2a, multicentrico, in aperto, a braccio singolo, in due stadi per la valutazione dell'efficacia, della sicurezza, della tollerabilità e della farmacocinetica di PF-06480605 in soggetti affetti da colite ulcerosa da moderata a grave.
16. Studio multicentrico di fase 3, randomizzato, in doppio cieco, controllato con placebo per valutare l'efficacia e la sicurezza di mongersen (GED-0301) per il trattamento di soggetti adulti e adolescenti con MDC in fase attiva.
17. Studio di estensione a lungo termine per la valutazione della sicurezza di filgotinib in soggetti affetti da colite ulcerosa.
18. Studi combinati di fase 3, in doppio cieco, randomizzati, controllati con placebo, per la valutazione dell'efficacia e della sicurezza di Filgotinib nell'induzione e nel mantenimento della remissione in soggetti con MDC attivo di grado da moderato a severo.
19. Studio di estensione a lungo termine per la valutazione della sicurezza di filgotinib in soggetti con malattia di Crohn.
20. Ruolo di Smad7 nella patogenesi della recidiva post chirurgica della Malattia di Crohn.

21. Studio di fase I/IIa, in aperto, a tre stadi, monocentrico per indagare la sicurezza, l'efficacia e la farmacocinetica di Niclosamide enema in soggetti affetti da proctite ulcerosa o proctosigmoidite ulcerosa in fase attiva.
22. Valutazione della proteina fragile X mental retardation (FMRP) come target terapeutico nel cancro del colon retto.
23. Ruolo dell'acido urico nell'infiammazione intestinale.
24. Valutazione dell'attività anti-tumorale del composto anti-elmintico rafoxanide nel cancro del colon-retto.
25. Variazione dei parametri morfologici rilevati nell'ecografia intestinale in relazione alla terapia biologica e all'attività di malattia nei pazienti con malattia di Crohn.
26. Sperimentazione multicentrica, randomizzata, in doppio cieco, controllata verso placebo e di induzione per valutare l'efficacia e la sicurezza di Risankizumab in soggetti con malattia di Crohn in fase attiva e di grado da moderato a grave per cui è fallita una pregressa terapia con biologici.
27. Sperimentazione multicentrica, randomizzata, in doppio cieco, controllata verso placebo e di induzione per valutare l'efficacia e la sicurezza di Risankizumab in soggetti con malattia di Crohn in fase attiva e di grado da moderato a grave.
28. Sperimentazione multicentrica, randomizzata, in doppio cieco, controllata verso placebo e di mantenimento della durata di 52 settimane ed estensione in aperto per valutare l'efficacia e la sicurezza di Risankizumab in soggetti con malattia di Crohn che hanno ottenuto risposta al trattamento di induzione nello studio M16-006 oppure M15-991.
29. Smad7: un potenziale target molecolare nel trattamento del cancro coloretale.
30. Effetti del trattamento con inibitori dell'ATPasi in cellule T di pazienti con malattie infiammatorie croniche intestinali.
31. Indagine conoscitiva sulla sensibilità al glutine non celiaca.

COORDINAMENTO E DIRIGENZA DI ATTIVITA' CLINICHE ASSISTENZIALI

Documentata esperienza nella diagnosi e la gestione delle malattie digestive con particolare riguardo alla diagnosi e al monitoraggio delle malattie acido-correlate, delle malattie infiammatorie croniche intestinali, della malattia celiaca, dei disturbi funzionali dell' apparato digerente, delle malattie epatobiliari e nella diagnosi precoce, la stadiazione e il monitoraggio dei pazienti con neoplasie dell' apparato digerente nonché nella prevenzione e sorveglianza di soggetti ad alto rischio di neoplasie gastro-enteriche mediante l'utilizzo di molteplici tecniche, invasive e non, ed attraverso la collaborazione con altri gruppi di lavoro. Coordinamento e gestione delle emergenze gastroenterologiche ed, in particolare, delle emorragie digestive, ingestione di caustici o altri corpi estranei, processi infiammatori acuti delle vie biliari e del pancreas. Coordinamento ed attuazione di protocolli diagnostico-terapeutici assistenziali.

Gestione di risorse umane, programmazione e coordinamento di gruppi di lavoro per la diagnosi e il monitoraggio di patologie dell'apparato digerente e per la continuità assistenziale gastroenterologica. Responsabile e coordinatore nazionale ed internazionale di sperimentazioni cliniche di fase 1, fase 2 e fase 3 con farmaci innovativi per l'induzione ed il mantenimento delle fasi di remissione di malattie infiammatorie croniche intestinali, prevenzione di complicanze delle stesse, e per l'implementazione tecnologica di strumenti diagnostici. Implementazione dell'attività di ricerca clinica. Coordinamento nella realizzazione e gestione dei sistemi di qualità e certificazione ISO 9000.1. Analisi dettagliata e continuo monitoraggio degli indicatori della UOC di Gastroenterologia ed Endoscopia Digestiva, e capacità di attivare strategie correttive al fine del raggiungimento degli obiettivi preposti. Direttore Medico del centro di Fase 1 per sperimentazioni umane presso il Policlinico Tor Vergata.

ATTIVITA' SCIENTIFICA

L'attività scientifica è stata svolta, in qualità di Responsabile, nel laboratorio della Cattedra di Gastroenterologia, Dipartimento di Medicina dei Sistemi, Università degli Studi Tor Vergata di Roma, con costante supervisione dei dottorandi ed assegnisti di ricerca, ed in collaborazione con i seguenti centri di ricerca nazionale ed internazionale:

1. Laboratorio di Immunologia dell'Istituto Superiore di Sanità, Roma, diretto dalla Dott.ssa Monica Boirivant;
2. Laboratorio di Immunologia, della Facoltà di Medicina e Chirurgia, dell'Università degli Studi Tor Vergata di Roma, diretto dal Prof. Roberto Testi;
3. Laboratorio di Gastroenterologia del Dipartimento di Internistica Clinica e Sperimentale-Gastroenterologia, II Università di Napoli, Prof. Marco Romano;
4. Unità di Anatomia Patologica, della Facoltà di Medicina e Chirurgia, dell'Università degli Studi Tor Vergata di Roma, Prof. Piero Palmieri.
5. Laboratorio di Immunologia, I. Medical Clinic, University of Mainz, Germania, diretto dal Prof. Markus Neurath;
6. Laboratori della Divisione di Infection, Inflammation and Repair, University of Southampton, Southampton, UK, diretti dal Dr Sylvia Pender;
7. Laboratorio del Dipartimento di Medicina Interna, della Facoltà di Medicina e Chirurgia, dell'Università degli Studi Tor Vergata di Roma, diretto dal Prof. Giorgio Federici.
8. Cattedra di Pediatria, della Facoltà di Medicina e Chirurgia, dell'Università degli Studi "La Sapienza" di Roma, Prof. Salvatore Cucchiara
9. Laboratorio del Dipartimento di Medicina Sperimentale della Facoltà di Medicina e Chirurgia, dell'Università degli Studi Magna Graecia, di Catanzaro, Prof. Francesco Luzzu.
10. Laboratorio di Dermatologia del Dipartimento di Medicina Interna, Università di Roma "Tor Vergata", Roma, Prof. Sergio Chimenti e Prof. A. Costanzo.

11. Centro per lo Studio e la Cura della Malattia Celiaca, Fondazione IRCCS Policlinico San Matteo, Università di Pavia, Prof. G Corazza e Prof. A. Di Sabatino.
12. Unità di Gastroenterologia, Fondazione IRCCS Ca' Granda - Ospedale Maggiore Policlinico, Milano, Dott. F. Caprioli.
13. Laboratorio di Immunologia, Universite Rene Descartes Paris 5, INSERM U580, Hopital Necker-Enfants Malades, Parigi, diretto dal Dr. Lucienne Chatenoud.
14. Mucosal Immunity Section, Laboratory of Host Defenses, National Institute of Allergy and Infectious Diseases, NIH, Bethesda, Maryland, USA, diretto dal Dr. Warren Strober.
15. Institute of Cell and Molecular Science, Barts and the London School of Medicine and Dentistry, London, UK, diretto dal Prof. Thomas T MacDonald.

L'attività scientifica è consistita in:

1. RICERCHE DI FISILOGIA DELL'IMMUNITÀ MUCOSALE NELL'INTESTINO UMANO
2. RICERCHE DI IMMUNOLOGIA CLINICA ED IMMUNOPATOLOGIA DELLE MALATTIE DIGESTIVE
3. CLINICA DELLE MALATTIE INFIAMMATORIE CRONICHE INTESTINALI, DELLA MALATTIA CELIACA E DELL'INFEZIONE DA *HELICOBACTER PYLORI*
4. STUDI DI CARCINOGENESI
5. SVILUPPO DI NUOVI FARMACI IMMUNOMODULATORI

PUBBLICAZIONI

I risultati dell'attività scientifica sono riassunti in pubblicazioni in extenso apparse in riviste scientifiche con "peer review" citate nel Science Citation Index e/o Current Contents Life Sciences ed oltre 500 lavori in forma di abstracts.

Indice h di Hirsch (scopus): 85

Elenco Pubblicazioni in extenso su riviste internazionali recensite:

1. **PALLONE F, BOIRIVANT M, FAIS S, LUZZA F, DOLDO P, MONTELEONE G, ALOI A.** ANTIBACTERIAL DRUGS IN CROHN'S DISEASE. *Ital J Gastroenterol.* 1992 Nov-Dec;24(9 Suppl 2):17-8.
2. **BIANCONE L, SCOPINARO F, MALETTA M, MONTELEONE G, LUZZA F, BANCİ M, MERCANTINI P, TRENDİ T, PALLONE F.** CIRCULATING D DIMER IN INFLAMMATORY BOWEL DISEASE. *ITAL J OF GASTROENTEROL* 1994; 26:116-120.
3. **LUZZA F, IMENEO M, MALETTA M, MONTELEONE G, DOLDO P, BIANCONE L, PALLONE F.** ISOTYPIC ANALYSIS OF SPECIFIC ANTIBODY RESPONSE IN SERUM, SALIVA, GASTRIC AND RECTAL HOMOGENATES OF *HELICOBACTER PYLORI*-INFECTED PATIENTS. *FEMS IMMUNOLOGY AND MEDICAL MICROBIOLOGY* 1995; 10: 285-288.
4. **MONTELEONE G, MARASCO R, PARRELLO T, DE MEDICI A, GIGLIO A, DOLDO P, LUZZA F, PALLONE F.** LOW PREVALENCE OF P-ANCA IN UNAFFECTED RELATIVES OF PATIENTS WITH ULCERATIVE COLITIS FROM A MEDITERRANEAN AREA. *INFLAMMATORY BOWEL DISEASES* 1996, 1: 11-15.
5. **PIETRAVALLE P, MONTELEONE G, MORANO S, CRISTINA G, DE ROSSI MG, SAGRATELLA E, BIANCONE L, PARRELLO T, OLIVA A, PALLONE F, DI MARIO U.** ANTINEUTROPHIL

CYTOPLASMIC ANTIBODIES ARE PRESENT IN LONG STANDING TYPE 1 DIABETICS BUT DO NOT CORRELATE WITH SELECTIVE PROTEINURIA. J AUTOIMMUNITY 1996; 9: 113-117.

6. **ROSA M, ESPOSITO C, CAGLIOTI A, MAZZA G, CAPRIA M, COMI N, MONTELEONE G, SINICO RA, FUIANO G.**
DOES THE PRESENCE OF ANCA IN PATIENTS WITH ULCERATIVE COLITIS NECESSARILY IMPLY RENAL INVOLVEMENT? NEPHROLOGY DIALYSIS TRANSPLANTATION 1996; 11: 2426-2429.
7. **LUZZA F, MALETTA M, IMENEO M, MONTELEONE G, MARASCO R, BIANCONE L, PALLONE F.** EVIDENCE AGAINST COLONIC MUCOSA COLONISATION BY HELICOBACTER PYLORI. LACK OF A SPECIFIC ANTIBODY RESPONSE IN HOMOGENATES OF RECTAL ENDOSCOPIC BIOPSIES. ITAL J OF GASTROENTEROL 1996; 28: 447-451.
8. **PALLONE F, MONTELEONE G.** REGULATORY CYTOKINES IN INFLAMMATORY BOWEL DISEASE. ALIMENT PHARMACOL THER 1996; 10 (SUPPL 2): 75-79.
9. **PALLONE F, FAIS S, MONTELEONE G.** INTERFERON-GAMMA FOR TREATING CROHN'S DISEASE: DO WE KNOW WHAT IS HELFUL AND WHAT IS HARMFUL? ITAL J GASTROENTEROL HEPATOL 1997; 29: 406-408.
10. **MONTELEONE G, BIANCONE L, MARASCO R, MARASCO O, LUZZA F, PALLONE F.** IL-12 IS EXPRESSED AND ACTIVELY RELEASED BY CROHN'S DISEASE (CD) LAMINA PROPRIA MONONUCLEAR CELLS (LPMC). GASTROENTEROLOGY 1997; 112: 1169-1178.
11. **PARRELLO T, PAVIA M, ANGELILLO IF, MONTELEONE G, RIEGLER G, PAPI G, D' INCÀ R, ANNESE V, TONELLI F, CAPRILLI R, PALLONE F AND THE ITALIAN GROUP FOR THE STUDY OF THE COLON AND RECTUM (GISC).** APPENDECTOMY IS AN INDEPENDENT PROTECTIVE FACTOR FOR ULCERATIVE COLITIS: RESULTS OF A MULTICENTRE CASE CONTROL STUDY. ITAL J OF GASTROENTEROL 1997; 29: 208-213.
12. **LUZZA F, IMENEO M, MALETTA M, GRAZIANO P, MARASCO R, MONTELEONE G, CARADONNA M, PALLONE F.** EVALUATION OF A COMMERCIAL SEROLOGICAL KIT FOR DETECTION OF SALIVARY IMMUNOGLOBULIN G TO HELICOBACTER PYLORI. EUR J CLIN MICROBIOL INFECT DIS 1997; 16: 775-777.
13. **PALLONE F, MONTELEONE G.** INTERLEUKIN 12 AND TH1 RESPONSES IN INFLAMMATORY BOWEL DISEASE. GUT 1998; 43: 735-736.
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PREMI

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Premio Tilde Fiorentini” award 2000

Premio “Aldo Torsoli” 2005

Premio Scanno per la Medicina , XLIII edizione, 2016

Medaglia d'oro al merito della sanità pubblica conferita dal Presidente Sergio Mattarella, Roma, 2016.

Premio Recti Eques Paladini Italiani della Salute 2025

RESPONSABILITA' SCIENTIFICA DI PROGETTI DI RICERCA FINANZIATI DA ISTITUZIONI, ENTI o SOCIETA'

1. Broad Medical Research Program: 2004-2005- Role of Smad7, an inhibitor of TGF-beta1 signalling, in chronic intestinal Inflammation –
2. Ministero dell' Istruzione, dell' Università e della Ricerca, Italy, 2004-2006, -Expression and regulation of foxp3-regulatory cells in inflammatory bowel disease- .
3. Associazione Italiana per la Ricerca sul Cancro: 2004–2007 Chemoprophylactic effect of mesalazine in colorectal cancer.
4. Broad Medical Research Program: 2005-2007- Interleukin-21 triggers inflammatory pathways in the gut: relevance for human inflammatory bowel diseases-
5. Istituto Superiore di Sanità, 2006. Strategie di uso di batteri probiotici, prodotti batterici e parassitari per la terapia delle malattie autoimmuni ed allergiche.
6. SEVENTH FRAMEWORK PROGRAMME, EUROPEAN UNION, No. 200931: Mucosal proteases and their inhibitors in inflammatory bowel disease: From etiopathogenetic insight to innovative therapy. 2008-2011.
7. SEVENTH FRAMEWORK PROGRAMME, EUROPEAN UNION, No. 202020, IPODD. IBD: Protease offer new targets for drug discovery.
8. Broad Medical Research Program: 2008-2010- Antagonistic effects of Interleukin-25 on CD14+ cell cytokine responses in the gut.
9. Associazione Italiana per la Ricerca sul Cancro: 2009–2012 REGULATION OF COLON CARCINOGENESIS BY 2-METHOXY-5-AMINO BENZOYLHYDROXAMIC ACID, A

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10. Broad Medical Research Program: 2010-2012-Effect of Smad7 antisense oligonucleotide on clinical, laboratory and immunological variables in patients with active Crohn's disease: the first human experience.
11. Associazione Italiana per la Ricerca sul Cancro: 2013–2016 Smad7 as a molecular target for pharmacological intervention in colorectal cancer.
12. Bill & Melissa Gates Foundation: "Identification of novel biomarkers for environmental enteropathy in children using an evidenced based approach" 26/05/2015 28/02/2017
13. Associazione Italiana Celiachia: 2016-2018: ROLE OF mTOR KINASE CASCADE IN CELIAC DISEASE.
14. Associazione Italiana per la Ricerca sul Cancro: 2017-2019: Interleukin-34 sustains pro-tumorigenic signals in colon cancer tissue.
15. Ministero dell' Istruzione, dell' Università e della Ricerca, Italy "Decoding the cross-talk between immune metabolism and the environmental sensor Aryl hydrocarbon receptor (AHR), for novel immunotherapeutic strategies against inflammatory and tumor diseases. 2019-2022.
16. Ministero dell' Istruzione, dell' Università e della Ricerca, Italy "PRIN-2022 PNRR Prot. P2022Y47YC "Bromodomain-containing protein 4 as a novel positive regulator of gut inflammation and immune target for innovative therapeutics in inflammatory bowel diseases (P2022Y47YC); 2023-2025
17. PRIN HEAL ITALIA - PE6 (PE_00000019) 2023-2025.
18. Ministero della Salute: PNRR-MCNT2-2023-12377866. Identification of new predictive and therapeutic targets to treat colorectal cancer. 2024-2026.

CONTRATTI

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2. Giuliani "Ruolo dell'IL-21 nella modulazione della risposta immunitaria in corso di malattie infiammatorie intestinali" 20/04/2007 31/12/2011 € 72.600,00
3. IPODD "IBD: proteases offer new targets for drug discovery" 01/06/2008 01/06/2008 € 118.200,00
4. IBDase "Mucosal proteases and their inhibitors in inflammatory bowel disease: From etipathogenetic insight to innovative therapy" 01/03/2008 28/02/2011, 02/01/2014 31/12/2016 € 175.400,00
5. Sofar "Effetti modulatori del lattobacillo casei sulla espressione di triptasi e tripsina in

- pazienti con sindrome dell'intestino irritabile" 10/03/2008 10/03/2009 € 24.000,00
6. Airc "Regulation of colon carcinogenesis by 2-methoxy-5-amino benzoylhydroxamic acids, a derivate of mesalazine" 11/11/2009 30/12/2012 € 240.000,00
 7. Teva "Modulation of Gut Inflammation by Laquinimod" 17/06/2011 31/12/2011 € 30.000,00
 8. Broad "Gli effetti dell'oligonucleotide antisense Smad7 nelle variabili cliniche di laboratorio e immunologiche in pazienti con malattia di Crohn" 02/01/2012 02/01/2012 € 142.656,00
 9. Sirtris "Modulation of Gut Inflammation and colitis-associated colon cancer by Sir1 activators" 02/01/2012 31/12/2013 \$ 84.000,00
 10. Sofar "Effetti modulatori del lattobacillo casei sulla espressione di triptasi e tripsina in pazienti con sindrome dell'intestino irritabile" 01/02/2012 01/02/2013 € 36.300,00
 11. Lycera "ATPase Inhibitor Effects on T cells from Subjects with Inflammatory Bowel Disease" 02/01/2013 31/12/2013 \$ 100.000,00
 12. Airc "Smad7 as a molecular target for pharmacological intervention in colorectal cancer" 02/01/2013 02/01/2015 € 240.000,00
 13. Giuliani "Effetto modulatorio di Smad7 in linee cellulari di cancro del colon-retto" 07/01/2013 07/01/2016 € 72.600,00
 14. Lycera "ATPase Inhibitor Effects on T cells from Subjects with Inflammatory Bowel Disease" 27/01/2015 26/09/2015 \$ 100.000,00
 15. Bill & Melissa Gates Foundation: "Identification of novel biomarkers for environmental enteropathy in children using an evidenced based approach" 26/05/2015 28/02/2017 \$ 135.000,00
 16. PPMServices "Ruolo di Smad7 nel processo di ri-epitelizzazione della mucosa intestinale" 30/10/2015 30/10/2018 € 150.000,00
 17. PPMServices "Analisi degli effetti infiammatori e tumorali dell'interleukina-34 nell'intestino" 30/10/2015 30/10/2018 € 150.000,00
 18. PPMServices "Ruolo di Smad7 nel processo fibrotico intestinale" 30/10/2015 30/10/2018 € 150.000,00
 19. PPMServices "Modulazione di processi infiammatori, fibrotici e tumorali intestinali ad opera di attivatori chimici NPD-0614 di aryl hydrocarbon receptor" 30/10/2015 30/10/2018 € 150.000,00
 20. PPMServices "Evoluzione delle concentrazioni sieriche di CCL20 in soggetti affetti da morbo di Crohn" 30/10/2015 30/10/2018 € 150.000,00
 21. Aic "Role of mTor kinase cascade in celiac disease" 08/03/2016 07/03/2019 € 155.295,00
 22. Celgene "A phase 2 open-label study to explore the pharmacodynamic and clinical effects of Mongersen (GED-0301) in subjects with active Crohn's disease" 10/03/2016 € 52.100,00
 23. Uni Tor Vergata Consolidate the Foundation 2015 "Novel therapeutic targets in colon cancer" 15/06/2016 15/03/2018 € 18.700,00
 24. Airc "Interleukin-34 sustains pro-tumorigenic signals in colon cancer tissue" 02/01/2017

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25. "Ficz, un ligando naturale di Aryl Hydrocarbon Receptor, come modulatore della fibrosi intestinale" 10/07/2017 € 99.205,61
26. Galapagos "Il ruolo di Sik nella modulazione dei segnali infiammatori dell'intestino" 31/01/2019 € 130.000,00
27. Ministero dell' Istruzione, dell' Università e della Ricerca, Italy "PRIN-2022 PNRR Prot. P2022Y47YC "Bromodomain-containing protein 4 as a novel positive regulator of gut inflammation and immune target for innovative therapeutics in inflammatory
28. Ministero della Salute: PNRR-MCNT2-2023-12377866. Identification of new predictive and therapeutic targets to treat colorectal cancer. 2024-2026; € 1.000.000,00

INVENTORE DEI SEGUENTI BREVETTI

1. ANTISENSE OLIGONUCLETIDES AGAINST SMAD7 AND USES THEREOF IN THE MEDICAL FIELD PCT Pub. No. WO2004/087920; Grant_Date 19/12/2007; Inventors Giovanni Monteleone.
2. Epitopi antigenici dell'Interleuchina 21, anticorpi relativi e loro uso in campo medico. Filing_date 29/11/2004 Patent_number 1351588; Grant_Date 13/01/2009; Inventors Giovanni Monteleone.
3. A treatment for inflammatory disease. Filing_date 04/04/2008; Patent_number EP2106801; Inventors Monteleone Giovanni.
4. Binding proteins and methods of making and using same; Filing_date 28/04/2008; Application_no EP08425294.9; Inventors Monteleone Giovanni.
5. Treatments for inflammatory disease; Filing_date 06/06/2008; Application_no EP08157799.1; Inventors Monteleone Giovanni.
6. Methods for preventing or reducing carcinogenesis; Filing_date 01/07/2009; PCT App. No. PCT/EP2009/008633. Inventors Bellinva Salvatore, Baroni Sergio, Monteleone Giovanni, Viti Francesca
7. METHODS FOR PREDICTING RESPONSIVENESS TO ANTI-SMAD7 THERAPY
8. METHODS OF TREATING DIABETES AND/OR PROMOTING SURVIVAL OF PANCREATIC ISLETS AFTER TRANSPLANTATION
9. Filing Date 18th April 2012
10. Inventors: Giovanni Monteleone, Peter Buchwald, Luca Inverardi, Antonello Pileggi, Camillo Ricordi, Alice Tomei. WO 2013158868 A1

SVILUPPO DI PRODOTTI FARMACOLOGICI

La ricerca scientifica ha contribuito allo sviluppo di un prodotto farmacologico, contenente un oligonucleotide antisense contro Smad7, somministrabile per via orale, somministrato per la prima volta nell' uomo in uno studio di fase 1 e successivamente in studi multicentrici di fase 2 e di fase 3, in pazienti con malattia di Crohn attiva.

“Autorizzo il trattamento dei miei dati personali ai sensi del Regolamento (UE) 2016/679 (GDPR) e del D.Lgs. 196/2003 e successive modifiche, per le finalità connesse alla gestione e al controllo delle attività di sperimentazione animale e all'accesso alle strutture dello stabulario.”

Roma

01.04.2026

F.to Prof. Giovanni Monteleone

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