



Safety and Efficacy Trial of RPC1063 for Moderate to Severe Ulcerative Colitis

CLINICALTRIALS.GOV IDENTIFIER
NCT02435992

RECRUITMENT STATUS
COMPLETED

FIRST POSTED
MAY 6, 2015

LAST UPDATE POSTED
JULY 9, 2020

STUDY DESCRIPTION

Brief Summary

The purpose of this study is to determine whether RPC1063 is effective in the treatment of Ulcerative Colitis (UC).

Condition or Disease: Ulcerative Colitis

Intervention/treatment: Drug: RPC1063
Drug: Placebo

Phase: Phase 3

DETAILED DESCRIPTION

The trial is composed of 2 periods: Induction and Maintenance. In the Induction Period (IP), patients will be entered into the trial in 3 separate cohorts (Cohort 1 and Cohort 2 for adults, Cohort 3 for adolescents). Patients from Cohort 1, 2, and 3 in clinical response at the end of the IP will proceed through to the Maintenance Period (MP). Patients from Cohort 1, 2, and 3 who participate in this trial may also qualify to participate in an optional Open-Label Extension (OLE) trial.

STUDY DESIGN

Study Type: Interventional

Estimated Enrollment : 1012 participants

Intervention Model : Parallel Assignment

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Primary Purpose: Treatment

Official Title: A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Trial of Oral RPC1063 as Induction and Maintenance Therapy for Moderate to Severe Ulcerative Colitis

Actual Study Start Date: June 2015

Actual Primary Completion Date: March 2020

Actual Study Completion Date: June 2020

ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Experimental: RPC1063 (Ozanimod) 1mg, daily oral administration during Induction and Maintenance periods.	Drug: RPC1063
Placebo Comparator: Placebo Daily oral administration during Induction and Maintenance periods.	Drug: Placebo

OUTCOME MEASURES

Primary Outcome Measures: 1. Clinical remission assessed by Mayo component sub-scores [Time Frame: Week 10]
Induction Period
2. Clinical remission assessed by Mayo component sub-scores [Time Frame: Week 52]
Maintenance Period

ELIGIBILITY CRITERIA

Ages Eligible for Study: 12 to 75 Years (Child, Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Aged 18 to 75 years (at screening for Cohort 1 and 2)

- Male or female adolescent patients aged 12 to < 18 years (at screening) with a body weight greater than or equal to 45 kg - UC confirmed on endoscopy -

Moderately to severely active UC (May score 6-12) - Currently receiving treatment with aminosalisylate, prednisone, or budesonide - Can be receiving

azathioprine, mercaptopurine, or methotrexate, but treatment will be stopped prior to randomization Exclusion Criteria: - Have severe extensive colitis as

evidence by: - Physician judgment that the patient is likely to require colectomy or ileostomy within 12 weeks of baseline. - Current or recent (within 3 months)

evidence of fulminant colitis, toxic megacolon, or bowel perforation. - Diagnosis of CD, indeterminate colitis, or the presence of fistula consistent with CD or

microscopic colitis, radiation colitis, or ischemic colitis - Clinically relevant cardiovascular conditions or other relevant diseases that could impact the

implementation or interpretation of the trial, or put the patient at risk - History of uveitis or unknown macular edema - Pregnancy, lactation, or a positive serum

β-human chorionic gonadotropin (β-hCG) measured during screening

CONTACTS AND LOCATIONS**Contacts****Locations**

United States, Arizona	Arizona Digestive Health	Sun City
United States, Arizona	Adobe Clinical Research LLC	Tucson
United States, Arkansas	Arkansas Gastroenterology, P.A.	North Little Rock
United States, California	Anaheim Clinical Trials	Anaheim
United States, California	Aurora Care Clinic	Costa Mesa
United States, California	Valley View Internal Medicine	Garden Grove
United States, California	Davita Clinical Trials, LLC	Huntington Beach
United States, California	University of California San Diego Medical Center	La Jolla
United States, California	OM Research	Lancaster
United States, California	University of Southern California - Keck School of Medicine	Los Angeles
United States, California	Southern California Research Institute Medical Group, Inc.	Los Angeles
United States, California	Gastrointestinal Biosciences	Los Angeles
United States, California	UCLA Medical Center	Los Angeles
United States, California	Facey Medical Foundation (Parent)	Mission Hills
United States, California	Alliance Clinical Research, LLC	Oceanside
United States, California	Medical Associates Research Group, Inc.	San Diego
United States, California	University of California at San Francisco (PARENT)	San Francisco
United States, Connecticut	Medical Research Center of Connecticut, LLC	Hamden
United States, Florida	Gastro Florida	Clearwater
United States, Florida	Clinical Research of West Florida Inc - Clearwater	Clearwater
United States, Florida	Advanced Pharma Research, Inc	Delray Beach
United States, Florida	Universal Axon Clinical Research	Doral
United States, Florida	Dolphin Medical Research	Doral
United States, Florida	South Florida Clinical Trials	Hialeah
United States, Florida	Florida Center for Gastroenterology	Largo
United States, Florida	City Medical Group	Miami
United States, Florida	Advanced Clinical Research	Miami
United States, Florida	Advanced Clinical Research of Miami	Miami
United States, Florida	Regenerate Clinical Trials	Miami
United States, Florida	Advanced Research for Health Improvement	Naples
United States, Florida	Advanced Research Institute, Inc.	New Port Richey
United States, Florida	NSB Research	New Smyrna Beach
United States, Florida	Harmony Clinical Research	North Miami Beach
United States, Florida	Med-Care Research	North Miami Beach

United States, Florida	Center For Digestive Health	Orlando
United States, Florida	IMIC, Inc.	Palmetto Bay
United States, Florida	DBC Research, Corp	Pembroke Pines
United States, Florida	Theia Clinical Research, LLC	Pinellas Park
United States, Florida	Florida Medical Clinic, P.A.	Zephyrhills
United States, Georgia	Atlanta Gastroenterology Associates LLC	Atlanta
United States, Georgia	Gastrointestinal Specialists of Georgia, PC	Marietta
United States, Idaho	Grand Teton Research Group, PLLC	Idaho Falls
United States, Illinois	Northwestern University Feinberg Sch of Medicine Division of Gastroenterology	Chicago
United States, Illinois	University of Chicago Medical Center	Chicago
United States, Illinois	DM Clinical Research	Oak Lawn
United States, Illinois	Carle Foundation Hospital	Urbana
United States, Indiana	Indiana University Hospital	Indianapolis
United States, Kansas	Cotton-O'Neil Clinical Research Center, Digestive Health	Topeka
United States, Kentucky	University of Kentucky Medical Center	Lexington
United States, Kentucky	University of Louisville	Louisville
United States, Louisiana	Gastroenterology Associates, LLC	Baton Rouge
United States, Maryland	University of Maryland Medical Group	Baltimore
United States, Maryland	Woodholme Gastroenterology	Baltimore
United States, Maryland	Johns Hopkins Clinical Research Network	Baltimore
United States, Maryland	Chevy Chase Clinical Research	Chevy Chase
United States, Maryland	Gastro Center of Maryland	Columbia
United States, Maryland	Charm City Research Group	Towson
United States, Massachusetts	Boston Medical Center	Boston
United States, Massachusetts	Commonwealth Clinical Studies, PLLC.	Brockton
United States, Massachusetts	Community Clinical Research Network	Marlborough
United States, Michigan	University of Michigan Health System	Ann Arbor
United States, Michigan	Center For Digestive Health	Troy
United States, Minnesota	Mayo Clinic	Rochester
United States, Missouri	Ehrhardt Clinical Research, LLC	Belton
United States, Missouri	Clinical Research Professionals, LLC - De Paul Medical Dr	Bridgeton
United States, Missouri	Washington University	Saint Louis
United States, Missouri	Clinical Research Professionals LLC - The Pines Court	Saint Louis
United States, Missouri	Clinical Research Professionals, LLC - Olde Cabin Rd	Saint Louis
United States, Missouri	Mercy Research	Springfield
United States, New Hampshire	Mary Hitchcock Memorial Hospital	Lebanon
United States, New York	Montefiore Medical Center	Bronx
United States, New York	NY Scientific	Brooklyn
United States, New York	Long Island Clinical Research Associates	Great Neck
United States, New York	Icahn School of Medicine Mount Sinai Beth Isreal	New York
United States, New York	Concord Medical Group PRIME	New York
United States, New York	New York University School of Medicine	New York
United States, New York	Weill Cornell Medical College	New York
United States, New York	Mount Sinai - PRIME	New York
United States, North Carolina	Asheville Gastroenterology Associates, P.A.	Asheville

United States, North Carolina	University of North Carolina at Chapel Hill	Chapel Hill
United States, North Carolina	Carolinas HealthCare System Digestive Health	Charlotte
United States, North Carolina	East Carolina Gastroenterology, PA	Jacksonville
United States, North Carolina	Kinston Medical Specialists, PA	Kinston
United States, North Carolina	PMG Research of Rocky Mount, LLC	Rocky Mount
United States, Ohio	UC Health Clinical Trials Office	Cincinnati
United States, Ohio	The Cleveland Clinic Foundation	Cleveland
United States, Ohio	Ohio State University Clinical Trials Management Office	Columbus
United States, Ohio	Clinical Inquest Center Ltd	Springfield
United States, Oklahoma	University of Oklahoma	Oklahoma City
United States, Oklahoma	Digestive Disease Specialists	Oklahoma City
United States, Oregon	Oregon Health & Science University	Portland
United States, Pennsylvania	Hospital of the University of Pennsylvania	Philadelphia
United States, South Carolina	Consultants in Gastroenterology, PA	Columbia
United States, South Carolina	Gastroenterology Associates of Orangeburg	Orangeburg
United States, Tennessee	Gastro One	Germantown
United States, Tennessee	Vanderbilt University Medical Center	Nashville
United States, Texas	Baylor Research Institute	Dallas
United States, Texas	Brooke-Army Medical Center	Fort Sam Houston
United States, Texas	Ventavia Research Group, LLC	Fort Worth
United States, Texas	Gulf Coast Research Group LLC	Houston
United States, Texas	The Methodist Hospital Research Institute	Houston
United States, Texas	Houston Endoscopy and Research Center	Houston
United States, Texas	Gastroenterology Research of San Antonio, LLC	San Antonio
United States, Texas	San Antonio Gastroenterology	San Antonio
United States, Texas	Texas Digestive Disease Consultants - Southlake	Southlake
United States, Texas	Spring Gastroenterology	Spring
United States, Texas	Digestive Health Specialists of Tyler	Tyler
United States, Utah	University of Utah	Salt Lake City
United States, Virginia	University of Virginia	Charlottesville
United States, Virginia	Gastroenterology Associates of Tidewater	Chesapeake
United States, Virginia	Gastroenterology, LTD	Virginia Beach
United States, Washington	Benaroya Research Institute at Virginia Mason	Seattle
United States, Washington	University of Washington Medical Center	Seattle
Argentina	Hospital Italiano	Buenos Aires
Argentina	Instituto DAMIC Fundacion Rusculleda	Cordoba
Argentina	Hospital Italiano de La Plata	La Plata
Argentina	Instituto Medico CER	Quilmes
Argentina	Instituto Medico de la Fundacion Estudios Clinicos	Rosario
Australia, New South Wales	Centre For Digestive Diseases	Five Dock
Australia, New South Wales	Nepean Hospital	Kingswood
Australia, Queensland	Mater Hospital Brisbane	South Brisbane
Australia, Queensland	Princess Alexandra Hospital	Woolloongabba
Australia, South Australia	Royal Adelaide Hospital	Adelaide
Australia, Victoria	Cabrini Hospital Malvern	Malvern

Australia, Victoria	The Alfred Hospital	Melbourne
Australia	Monash Medical Centre Clayton	Bentleigh East
Australia	Royal Prince Alfred Hospital	Camperdown
Austria	Medical University Vienna	Vienna
Belarus	Gomel Regional Clinical Hospital	Gomel
Belarus	City Clinical Hospital No 10	Minsk
Belarus	Vitebsk Regional Clinical Hospital	Vitebsk
Belgium	Imeldaziekenhuis	Bonheiden
Belgium	AZ Maria Middelaes	Gent
Belgium	Universitair Ziekenhuis Gent	Gent
Belgium	UZ Leuven	Leuven
Belgium	CHC - Clinique St-Joseph	Liege
Bulgaria	Medical Centre "Asklepii", OOD	Dupnitsa
Bulgaria	UMHAT 'Dr. Georgi Stranski', EAD	Pleven
Bulgaria	UMHAT "Kaspela", EOOD	Plovdiv
Bulgaria	MC Rusemed Ltd.	Ruse
Bulgaria	NMTH "Tsar Boris III"	Sofia
Bulgaria	MHAT "Lyulin", EAD	Sofia
Bulgaria	City Clinic UMHAC EOOD	Sofia
Bulgaria	MHAT 'Tokuda Hospital Sofia', EAD	Sofia
Bulgaria	UMHAT 'Tsaritsa Yoanna - ISUL', EAD	Sofia
Bulgaria	Fourth MHAT - Sofia EAD	Sofia
Bulgaria	UMHAT 'Sveta Anna' AD	Sofia
Bulgaria	UMHAT "SofiaMed", OOD	Sofia
Bulgaria	Medical Center "Nov Rehabilitatsionen Tsentar", EOOD	Stara Zagora
Bulgaria	MHAT 'Sv. Marina', EAD	Varna
Bulgaria	MC Medica Plus	Veliko Tarnovo
Canada, British Columbia	Vancouver General Hospital	Vancouver
Canada, Manitoba	Brandon Medical Arts Clinic	Brandon
Canada, Ontario	Viable Clinical Research - Lindsay	Lindsay
Canada, Ontario	LHSC - University Hospital	London
Canada, Ontario	LHSC - Victoria Hospital	London
Canada, Ontario	Humber River Hospital	Toronto
Canada, Ontario	Mount Sinai Hospital	Toronto
Canada, Ontario	Toronto Liver Centre	Toronto
Canada, Ontario	Toronto Digestive Disease Associates, Inc.	Vaughan
Canada, Quebec	Centre integre de sante et de services sociaux de la Monteregie-Centre - Hopital Charles-Le Moyne	Greenfield Park
Canada, Quebec	The Ottawa Hospital - General Campus	Ottawa
Canada, Quebec	CHUS - Hôpital Fleurimont	Sherbrooke
Croatia	Clinical Hospital Center Osijek	Osijek
Croatia	Clinical Hospital Centre Rijeka	Rijeka
Croatia	Clinical Hospital "Sveti Duh", Clinic of Internal Diseases	Zagreb
Croatia	Clinical Hospital Center Sestre milosrdnice Clinic of Internal Diseases	Zagreb
Croatia	Clinical Hospital Dubrava, Clinic of Internal Medicine, Department of Gastroenterology	Zagreb
Czechia	Vojenska nemocnice Brno	Brno

Czechia	Hepato-Gastroenterologie HK, s.r.o.	Hradec Kralove
Czechia	GASTRO JeKa s.r.o.	Klatovy
Czechia	Gregar s.r.o.	Olomouc
Czechia	PreventaMed	Olomouc
Czechia	ISCARE, a.s.	Prague 9
Czechia	Institut klinicke a experimentalni mediciny	Praha 4
Czechia	Thomayerova nemocnice	Praha 4
Czechia	Nemocnice Slany	Slany
Georgia	LTD Research Institute of Clinical Medicine	Tbilisi
Georgia	LLC Vivamedi	Tbilisi
Georgia	LTD Academician N.Kipshidze Central University Clinic	Tbilisi
Georgia	LTD Aversi Clinic	Tbilisi
Georgia	LTD Coloproctological Center	Tbilisi
Germany	Charite - Universitaetsmedizin Berlin Charité - Campus Benjamin Franklin	Berlin
Germany	Charite - Campus Virchow-Klinikum	Berlin
Germany	DRK Kliniken Berlin Westend	Berlin
Germany	Medical Care Unit Dachau	Dachau
Germany	Universitaetsklinikum Carl Gustav Carus TU Dresden	Dresden
Germany	Klinikum der Johann Wolfgang Goethe-Universitaet	Frankfurt
Germany	Crohn Colitis Centrum Rhein Main	Frankfurt
Germany	Universitaetsklinikum Freiburg	Freiburg
Germany	Universitaetsklinikum Hamburg-Eppendorf	Hamburg
Germany	Asklepios Klinik Hamburg	Hamburg
Germany	Medizinische Hochschule Hannover	Hannover
Germany	Universitaetsklinikum Koeln	Koeln
Germany	EUGASTRO GmbH	Leipzig
Germany	Universitaetsklinikum Schleswig-Holstein - Campus Luebeck	Luebeck
Germany	Universitaetsmedizin der Johannes Gutenberg-Universitaet Mainz	Mainz
Germany	Universitaetsklinikum Ulm	Ulm
Greece	Laiko General Hospital of Athens	Athens
Greece	University General Hospital of Heraklion	Heraklion
Greece	University General Hospital of Larissa	Larissa Thessaly
Greece	General Hospital of Thessaloniki Hippokratia	Thessaloniki
Greece	424th Army General Hospital	Thessaloniki
Hungary	DRC Gyogyszervizsgalo Kozpont Kft	Balatonfured
Hungary	Bekes Megyei Kozponti Korhaz Dr. Rethy Pal Tagkorhaz	Bekescsaba
Hungary	Obudai Egeszsegugyi Centrum Kft.	Budapest
Hungary	Magyar Honvedseg Egeszsegugyi Kozpont	Budapest
Hungary	Semmelweis Egyetem	Budapest
Hungary	Pannonia Maganorvosi Centrum	Budapest
Hungary	Szent Margit Korhaz	Budapest
Hungary	Debreceni Egyetem Klinikai Kozpont	Debrecen
Hungary	Bekes Megyei Kozponti Korhaz Pandy Kalman Tagkorhaza	Gyula
Hungary	Somogy Megyei Kaposi Mor Oktato Korhaz	Kaposvar
Hungary	Vasutegeszsegugyi Kft. - Debreceni Egeszsegugyi Kozpont	Letavertes

Hungary	Mohacsi Korhaz	Mohacs
Hungary	SzSzB Megyei Korhazak es Egyetemi Oktatokorhaz	Nyiregyhaza
Hungary	Fejer Megyei Szent Gyorgy Egyetemi Oktato Korhaz	Szekesfehervar
Israel	Wolfson Medical Center	Holon
Israel	Shaare Zedek Medical Center	Jerusalem
Israel	Meir Medical Center	Kfar Saba
Israel	Chaim Sheba Medical Center	Ramat Gan
Israel	Kaplan Medical Center	Rehovot
Israel	Tel Aviv Sourasky Medical Center	Tel Aviv
Italy	Azienda Ospedaliera Universitaria Policlinico Sant Orsola Malpighi	Bologna
Italy	Azienda Ospedaliera Universitaria Careggi	Firenze
Italy	Azienda Ospedaliero Universitaria San Martino	Genova
Italy	Azienda Socio Sanitaria Territoriale Fatebenefratelli Presidio Ospedale Sacco	Milano
Italy	A.O.U. Policlinico di Modena	Modena
Italy	Azienda Socio Sanitaria Territoriale di Monza (Presidio San Gerardo)	Monza
Italy	Azienda Ospedaliera Universitaria "Federico II"	Napoli
Italy	Fondazione IRCCS Policlinico San Matteo	Pavia
Italy	Azienda Ospedaliero Universitaria Pisana	Pisa
Italy	Complesso Integrato Columbus	Roma
Italy	Istituto Clinico Humanitas	Rozzano (MI)
Italy	IRCCS Ospedale Casa Sollievo della Sofferenza	San Giovanni Rotondo FG
Korea, Republic of	Inje University Haeundae Paik Hospital	Busan
Korea, Republic of	Yeungnam University Hospital	Daegu
Korea, Republic of	Konyang University Hospital	Daejeon
Korea, Republic of	Hanyang Univerisy Guri Hospital	Guri-si
Korea, Republic of	CHA Bundang Medical Center CHA University	Seongnam-si,
Korea, Republic of	Seoul National University Bundang Hospital	Seongnam
Korea, Republic of	Kyung Hee University Hospital	Seoul
Korea, Republic of	Seoul National University Hospital	Seoul
Korea, Republic of	Samsung Medical Center	Seoul
Korea, Republic of	Korea University Anam Hospital	Seoul
Korea, Republic of	Asan Medical Center	Seoul
Korea, Republic of	Kangbuk Samsung Hospital	Seoul
Korea, Republic of	Severance Hospital, Yonsei University	Seoul
Korea, Republic of	Ewha Womans University Mokdong Hospital	Seoul
Korea, Republic of	The Catholic University of Korea, St.Vicent's Hospital	Suwon
Korea, Republic of	Yonsei University Wonju Severance Christian Hospital	Wonju-Si
Latvia	Pauls Stradins Clinical University Hospital	Riga
Moldova, Republic of	"Sfanta Treime" Clinical Municipal Hospital	Chisinau
Moldova, Republic of	Clinical Hospital of the Ministry of Health, Department of Endoscopic Surgery	Chisinau
Moldova, Republic of	"Sf. Arhanghel Mihail" Municipal Clinical Hospital	Chisinau
Moldova, Republic of	Republican Clinical Hospital	Chisinau
Netherlands	Vrije Universiteit Medisch Centrum (VUMC)	Amsterdam
Netherlands	Academisch Medisch Centrum	Amsterdam
Netherlands	Universitair Medisch Centrum Groningen (UMCG)	Groningen

Netherlands	Maastricht University Medical Center	Maastricht
Netherlands	Zuyderland Medisch Centrum - Sittard-Geleen	Sittard-Geleen
Netherlands	ETZ Elisabeth	Tilburg
New Zealand	Christchurch Hospital NZ	Christchurch
New Zealand	Dunedin Public Hospital	Dunedin
Poland	Clinsante S.C. Osrodek Badan Klinicznych	Bydgoszcz
Poland	Specjalistyczna Przychodnia Lekarska Medicus	Chorzow
Poland	GLOBE Clinical Research Sp. z o.o. LLC	Klodzko
Poland	PLEJADY Sp. z o.o. (LLC) Medical Centre	Krakow
Poland	Centrum Medyczne A-Z Clinic	Kraków
Poland	Healthcare Center Orkan Med Stec Michalska Spolka Jawna	Ksawerow
Poland	Santa Familia Centrum Badan, Profilaktyki i Leczenia	Lodz
Poland	KO-MED Centra Kliniczne Lublin II	Lublin
Poland	Trialmed Llc	Piotrkow Trybunalski
Poland	SOLUMED Centrum Medyczne	Poznan
Poland	Specjalistyczna Praktyka Lekarska dr med. Marek Horynski	Sopot
Poland	KO-MED Centra Kliniczne Staszow	Staszow
Poland	GASTROMED Kopon, Zmudzinski and Partners Specialist Centre for Gastroenterology and Endoscopy, Spe	Torun
Poland	MDM Healthcare Centre	Warsaw
Poland	Nzoz Vivamed	Warsaw
Poland	Health Centre Metabolic Diseases Outpatient Clinic in Wierzoslawice	Wierzoslawice
Poland	LexMedica Osrodek Badan Klinicznych	Wroclaw
Romania	Bacau County Emergency Hospital, Department of Gastroenterology	Bacau
Romania	Hyperclinica MedLife Grivita	Bucharest
Romania	Bucharest University Emergency Hospital, Department of Internal Medicine II	Bucharest
Romania	TVM MED SERV SRL, Medical Center for Gastroenterology, Hepatology and Digestive Endoscopy	Cluj-Napoca
Romania	Sf. Apostol Andrei Constanta Emergency Clinical County Hospital	Constanta
Romania	Craiova County Emergency Clinical Hospital	Craiova
Romania	"Pius Brinzeu" County Emergency Clinical Hospital, Department of Gastroenterology and Hepatology	Timisoara
Russian Federation	Multidisciplinary Medical Clinic "Anthurium"	Barnaul
Russian Federation	Road Clinical Hospital on Station Irkutsk-Passazhirskiy of OJSC Russian Railways	Irkutsk
Russian Federation	SBEI HPE "Kazan State Medical University" of the MoH of the RF	Kazan
Russian Federation	FSBIH "Central Clinical Hospital of Russian Academy of Sciences"	Moscow
Russian Federation	SBIH of Nizhniy Novgorod region " Nizhniy Novgorod Regional Clinical Hospital n.a. N.A. Semashko"	Nizhniy Novgorod
Russian Federation	SBEIHPE Novosibirsk State Medical University	Novosibirsk
Russian Federation	FSBI "Scientific Research Institute of Physiology and Basic Medicine" under the SB of RAMS	Novosibirsk
Russian Federation	BHI of Omsk region "Clinical Oncology Dispensary"	Omsk
Russian Federation	SBEI HPE Rostov State Medical University of the MoH of the RF	Rostov-on-Don
Russian Federation	SBIH City Clinical Hospital #31	Saint Petersburg
Russian Federation	Union Clinic	Saint-Peterburg
Russian Federation	FSMEI HPE "Military Medical Academy n.a. S.M.Kirov"of Ministry of Defense of Russia	Saint-Petersburg
Russian Federation	SPb SBIH City Hospital # 26	Saint-Petersburg
Russian Federation	Pavlov First Saint Petersburg State Medical University	Saint-Petersburg
Russian Federation	Private Educational Institution of Higher Education "Medical University "REAVIZ"	Samara

Russian Federation	LLC Medical Company Hepatologist	Samara
Russian Federation	FFSBI "The Nikiforov Russian Center of Emergency and Radiation Medicine"	St. Petersburg
Russian Federation	SPb SBIH Alexandrovskaya City Hospital	St.Petersburg
Russian Federation	SBEI HPE "Stavropol State Medical Academy" MoH of RF	Stavropol
Russian Federation	Regional Clinical Hospital	Vladimir
Serbia	Clinical Hospital Center Bezanijska Kosa, Clinic of Internal Medicine	Belgrade
Serbia	Clinical Center of Serbia, Clinic of Gastroenterology and Hepatology, Department of Gastroenterology	Belgrade
Serbia	Clinical Hospital Center Zvezdara Clinic of Internal Diseases	Belgrade
Serbia	Military Medical Academy, Clinic of Gastroenterology and Hepatology	Belgrade
Serbia	Clinical Hospital Center Zemun Department of Gastroenterology	Belgrade
Serbia	Clinical Center Kragujevac, Clinic of Internal Medicine, Center for Gastroenterohepatology	Kragujevac
Serbia	Clinical Center Nis, Clinic of Gastroenterology and Hepatology	Nis
Serbia	General Hospital Djordje Jovanovic Zrenjanin	Zrenjanin
Slovakia	Fakultna nemocnica s poliklinikou F.D. Roosevelta	Banska Bystrica
Slovakia	Alian s.r.o.	Bardejov
Slovakia	PRO SANUS, a.s., Poliklinika ProCare Central	Bratislava
Slovakia	IBDcentrum s.r.o.	Bratislava
Slovakia	Slovak Research Center-team member, Sukromna gastroenterologicka ambulancia	Ilava
Slovakia	Gastroped s.r.o.	Kosice
Slovakia	Gastroenterologicka ambulancia MUDr. Peter Hegyi, s.r.o.	Malacky
Slovakia	PIGEAS s.r.o.	Martin
Slovakia	Nemocnica s poliklinikou S. Kukuru Michalovce, a.s.	Michalovce
Slovakia	Gastromedic s.r.o.	Nove Zamky
Slovakia	EndoCorp s.r.o.	Trnava
South Africa	Dr MJ Prins Practice	Cape Town
South Africa	Tiervlei Trial Centre	Cape Town
South Africa	Endocare Research	Cape Town
South Africa	Dr JP Wright Practice	Cape Town
South Africa	Dr YS Nanabhay Practice	Johannesburg
South Africa	Emmed Research	Pretoria
Spain	University Hospital Germans Trias i Pujol	Badalona
Spain	University Hospital of the Canary Islands (HUC) La Laguna	La Laguna
Spain	Hospital Universitario de Gran Canaria Dr. Negrin	Las Palmas de Gran Canaria
Spain	University Hospital Virgen del Rocío	Sevilla
Ukraine	RCI Chernivtsi Regional Clinical Hospital Dept of Gastroenterology Bukovinsky SMU	Chernivtsi
Ukraine	Dnipropetrovsk I.I. Mechnykov Regional Clinical Hospital	Dnipropetrovsk
Ukraine	Si Institute Of Gastroenterology Of Namsu Dept Of Stomach And Duodenum Diseases	Dnipropetrovsk
Ukraine	Ivano-Frankivsk City Clinical Hospital #1 Dep of Surgery SHEI Ivano-Frankivsk NMU	Ivano-Frankivsk
Ukraine	Central City Clinical Hospital Dept of Theraphy No. 2 SHEI Ivano-Frankivsk NMU	Ivano-Frankivsk
Ukraine	CI of PH Kharkiv CCH #2	Kharkiv
Ukraine	GI L.T.Malaya Therapy National Institute of the NAMS of Ukraine	Kharkiv
Ukraine	Kyiv City Clinical Hospital #1	Kyiv
Ukraine	SI Republican Clinical Hospital of the MOHU Dept of Gastroenterology O.O.Bogomolets NMU	Kyiv
Ukraine	CI of Kyiv RC Regional Clinical Hospital #2	Kyiv
Ukraine	Kyiv CCH #8 Dept of Gastroenterology P.L. Shupyk NMA of PGE	Kyiv

Ukraine	Kyiv CCH #18 Dept of Proctology O. O. Bogomolets NMU	Kyiv
Ukraine	Lviv Regional Clinical Hospital	Lviv
Ukraine	Communal City Clinical Hospital of Ambulance, Dept of Therapy #1 D.Halytskyi Lviv NMU	Lviv
Ukraine	CI Sumy City Clinical Hospital #1 Dept of Therapy Sumy SU	Sumy
Ukraine	Sumy Regional Clinical Hospital	Sumy
Ukraine	CI of TRC Ternopil University Hospital	Ternopil
Ukraine	A. Novak Transcarpathian Regional Clinical Hospital	Uzhgorod
Ukraine	MCIC MC LLC Health Clinic	Vinnitsia
Ukraine	Vinnitsia Regional Clinical Hospital for Invalids of the Great Patriotic War	Vinnitsia
Ukraine	M.I. Pyrogov VRCH Dept of Gastroenterology M.I. Pyrogov VNMU	Vinnitsia
Ukraine	Vinnitsia M.I. Pyrohov Regional Clinical Hospital	Vinnitsia
Ukraine	Vinnitsia M.I. Pyrohov National Medical University	Vinnitsia
Ukraine	City Clinical Hospital of Emergency and Urgent Care of Zaporizhzhya	Zaporizhia
Ukraine	Zaporizhia City Multispecialty Clinical Hospital #9, Department of Neurology	Zaporizhia
Ukraine	CI City Hospital #1	Zaporizhia
Ukraine	CI Zapor City Multifunctional CH#9 City Center of Gastroenterology SI Zapor MA of PGE of MOHU	Zaporizhzhia
Ukraine	Zaporizhia Regional Clinical Hospital	Zaporizhzhia
Ukraine	Central District Hospital under Zhytomyr District Council	Zhytomyr
United Kingdom	University Hospital Coventry	Coventry
United Kingdom	Royal Devon and Exeter Hospital (Wonford)	Exeter
United Kingdom	Gloucestershire Royal Hospital	Gloucester
United Kingdom	Whipps Cross University Hospital	London
United Kingdom	St Thomas' Hospital	London
United Kingdom	Royal Shrewsbury Hospital	Shrewsbury

Sponsors and Collaborators

Celgene

Investigator

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MORE INFORMATION

Responsible Party : Celgene
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