ISRCTN15874265 https://doi.org/10.1186/ISRCTN15874265

Study to assess the safety and effectiveness of remdesivir in people with severe COVID-19

Submission date
29/10/2020

Recruitment status
No longer recruiting

Registration date
03/11/2020

Overall study status
Completed

Last Edited
19/03/2021

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The purpose of this study is to test a new medicine, remdesivir (RDV) for people with COVID-19. There are no approved medications to treat COVID-19, a new disease caused by a virus called SARS-CoV-2 that was just identified in late 2019. COVID-19 can cause many symptoms. The symptoms can range from mild to very severe and sometimes can lead to death. The purpose of this study is to see if RDV can improve the health of people with severe COVID-19.

Who can participate?
Persons 12 years of age or older who have SARS-CoV-2 infection less than 4 days before joining the study, and are in hospital

What does the study involve?
Part A of this study included approximately 400 participants with severe COVID-19 infection. Part B of this study included approximately 5,600 participants also with severe COVID-19 infection. The treatment assignment for participants in Part B was based on whether or not they were on mechanical ventilation. The study doctor conducted a screening visit to make sure they could join the study.
Part A
Randomized study: The researchers used a computer program to randomly choose the treatment each participant took. This helped make sure the treatments were chosen fairly. Participants had an equal chance of receiving RDV for 5 days or RDV for 10 days. In both treatment arms, participants still received standard of care treatment.
Open label study: Each participant knew which treatment length they would get and the doctors and study staff also knew.

Part B was also open-label.
Participants who qualified for the study and decided to join received RDV by injections directly into the vein

Participants were followed up for 10 days.

What are the possible benefits and risks of participating?
Possible benefits: Participants may not get any benefit from taking part in this study. Studies are a way for doctors to see if a drug is useful in treating a disease. Taking part in this study may help us know more about how to treat people with COVID-19 in the future.
Possible risks: All medicines could potentially cause side effects in some people. Increases in levels of liver enzymes have been seen in some people who have taken RDV, which may be a sign of inflammation or damage to the cells in the liver.

Where is the study run from?
The study was run from Gilead Sciences, Inc. (USA) and took place at 173 centres globally.

When is the study starting and how long is it expected to run for?
February 2020 to June 2020

Who is funding the study?
Gilead Sciences, Inc. (USA)

Who is the main contact?
GileadClinicalTrials@gilead.com

Contact information

Type(s)
Scientific

Contact name
Ms Devi Sengupta

Contact details
333 Lakeside Drive
Foster City
California
United States of America
94404
+1 646-351-9642
Devi.SenGupta@gilead.com

Additional identifiers

ClinicalTrials.gov (NCT)
NCT04292899

Clinical Trials Information System (CTIS)
2020-000841-15

Integrated Research Application System (IRAS)
282007

Central Portfolio Management System (CPMS)
45460

Protocol serial number
GS-US-540-5773

Study information

Scientific Title
A phase 3 randomized study to evaluate the safety and antiviral activity of Remdesivir (GS-5734™) in participants with severe COVID-19

Study objectives
The odds of improvement for the 5-day treatment group (Treatment Group 1) is different from the odds of improvement for the 10-day treatment group (Treatment Group 2) with respect to clinical status assessed by a 7-point ordinal scale on Day 14

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/03/2020, North East - Tyne & Wear South Research Ethics Committee (HRA Jarrow, Room 001, Jarrow Business Centre, Rolling Mill Road, Jarrow, NE32 3DT, UK; +44 (0)207 1048084; nrescommittee.northeast-tyneandwearsouth@nhs.net), ref: 20/NE/0104

Primary study design
Interventional

Study design
Phase 3 randomized open-label multi-center study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection)

Interventions
The study was conducted in two parts.

In Part A, approximately 400 participants who met all eligibility criteria and who were not mechanically ventilated were randomized via an interactive web response system (IWRS) in a 1:1 ratio into one of the following treatment groups:
Treatment Group 1: continued standard of care therapy together with IV RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2, 3, 4, and 5
Treatment Group 2: continued standard of care therapy together with IV RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2, 3, 4, 5, 6, 7, 8, 9, and 10

After Part A completed enrollment, Part B enrolled up to 5600 additional participants, including some who were on mechanical ventilation. In Part B, participants who met all of the eligibility criteria were enrolled to receive the following (based on whether they were mechanically ventilated at enrollment):
Mechanically Ventilated Treatment Group: continued standard of care therapy together with IV

RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2, 3, 4, 5, 6, 7, 8, 9, and 10
Extension Treatment Group: continued standard of care therapy together with IV RDV 200 mg on Day 1 followed by IV RDV 100 mg on Days 2, 3, 4, 5, 6, 7, 8, 9, and 10
If the 5-day dosing regimen used in Treatment Group 1 of Part A is selected for Part B, all participants in the Extension Treatment Group and all new participants will be reassigned to receive treatment for a total of 5 days. National and local regulatory authorities will be informed.

All participants were followed-up for 28 days.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Remdesivir (RDV)

Primary outcome(s)
The odds of ratio for improvement on a 7-point ordinal scale on day 14, calculated from daily scores taken each day from baseline to day 14. (The ordinal scale is an assessment of the clinical status at a given day. The scale is as follows: 1. Death 2. Hospitalized, on invasive mechanical ventilation or Extracorporeal Membrane Oxygenation (ECMO) 3. Hospitalized, on non-invasive ventilation or high flow oxygen devices 4. Hospitalized, requiring low flow supplemental oxygen 5. Hospitalized, not requiring supplemental oxygen - requiring ongoing medical care (coronavirus (COVID-19) related or otherwise) 6. Hospitalized, not requiring supplemental oxygen - no longer required ongoing medical care (other than per protocol Remdesivir administration 7. Not hospitalized)

Key secondary outcome(s)
Adverse Events recorded from patient medical records from the time of consent up to Day 28 (+/-5 days). Serious adverse events were reported up to 30 days of last dose and after the protocol defined follow-up period if deemed relevant to the use of study drug.

Completion date
30/06/2020

Eligibility

Key inclusion criteria
1. Willing and able to provide written informed consent, or with a legal representative who can provide informed consent, or enrolled under ICH E6(R2) 4.8.15 emergency use provisions as deemed necessary by the investigator (participants ≥ 18 years of age), or willing and able to provide assent (participants ≥12 and <18 years of age, where locally and nationally approved) prior to performing study procedures. For participants ≥12 and <18 years of age, a parent or legal guardian willing and able to provide written informed consent prior to performing study procedures
2. Aged ≥ 18 years (at all sites), or aged ≥12 and <18 years of age weighing ≥40 kg (where permitted according to local law and approved nationally and by the relevant institutional review board [IRB] or independent ethics committee [IEC])
3. SARS-CoV-2 infection confirmed by PCR test ≤4 days before randomization

4. Currently hospitalized
5. SpO2 ≤94% on room air or requiring supplemental oxygen at screening
6. Radiographic evidence of pulmonary infiltrates
7. Men and women of childbearing potential who engage in heterosexual intercourse must agree to use protocol specified method(s) of contraception

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Total final enrolment
4891

Key exclusion criteria
1. Participation in any other clinical trial of an experimental treatment for COVID-19
2. Concurrent treatment with other agents with actual or possible direct-acting antiviral activity against SARS-CoV-2 <24 hours prior to study drug dosing
3. Evidence of multiorgan failure
4. Mechanically ventilated (including V-V ECMO) ≥5 days, or any duration of V-A ECMO
5. ALT or AST >5 ULN
6. Creatinine clearance <50 mL/min using the Cockcroft-Gault formula for participants ≥18 years of age and Schwartz Formula for participants <18 years of age
7. Positive pregnancy test
8. Breastfeeding woman
9. Known hypersensitivity to the study drug, the metabolites, or formulation excipient

Date of first enrolment
06/03/2020

Date of final enrolment
29/05/2020

Locations

Countries of recruitment
United Kingdom

England

Scotland

France

Germany

Hong Kong

Italy

Japan

Korea, South

Netherlands

Singapore

Spain

Sweden

Switzerland

Taiwan

United States of America

Uruguay

Study participating centre
Prince of Wales Hospital
Room G05, Ground Floor
30-32 Ngan Shing Street
Sha Tin
Hong Kong
Hong Kong
-

Study participating centre
Queen Mary Hospital
102 Pokfulam Road
2-10 Princess Margaret Hospital Road
Kowloon
Hong Kong
Hong Kong
-

Study participating centre

Tokyo Metropolitan Bokutoh Hospital
4-23-15 Kotobashi, Sumida-ku
Toyko
Japan
130-8575

Study participating centre
Yokohama Municipal Citizen's Hospital
1-1, Mitsuzawanishimachi, Kanagawa-ku,
Yokohama-shi,
Kanagawa
221-0855
Japan
221-0855

Study participating centre
Seoul Medical Center
156 Sinnae-ro, Jungnang-gu
Seoul, 2053
Korea, South
2053

Study participating centre
National Medical Center
245, Euljiro, Jung-gu
Seoul, 4564
Korea, South
4564

Study participating centre
National University Hospital
1E Kent Ridge Road,
NUHS Tower Block
119228
Singapore
119228

Study participating centre

Singapore General Hospital (SGH)
20 College Road
Singapore
169856

Study participating centre
National Centre for Infectious Diseases
16 Jalan Tan Tock Seng
Singapore
308442

Study participating centre
National Taiwan University Hospital
No.25, Lane 442, Sec.1, Jingguo Road,
Hsinchu City,
Hsinchu
Taiwan
30059

Study participating centre
Kaohsiung Veterans General Hospital
No. 386, Ta Chung 1st. Road,
Kaohsiung City
Taiwan
81362

Study participating centre
Hôpital Saint Antoine
184 rue du Faubourg Saint Antoine,
Paris,
France
75571

Study participating centre
Hôpital Saint-André
1 Rue Jean Burguet,
Service des maladies infectieuses et tropicales,
Bordeaux
France
3075

Study participating centre
Hôpital Saint Louis
1 Avenue Claude Vellefaux,
Paris,
France
75010

Study participating centre
Hôtel Dieu – Nantes
1 Place Alexis Ricordeau,
Service des Maladies Infectieuses et Tropicales
Nantes,
Loire-Atlantique
France
44093

Study participating centre
CHU Gui De Chauliac
80, avenue Augustin Fliche, Montpellier,
France
34295

Study participating centre
Universitatsklinikum
Dusseldorf, Moorenstraße 5, Düsseldorf
Germany
40225

Study participating centre
Klinikum St. Georg gGmbH
Delitzscher Strasse 141, Leipzig
Sachsen
Germany
4129

Study participating centre
Universitätsklinikum Hamburg Eppendorf
Martinistraße 52,
I. Medizinische Klinik und Poliklinik,Hamburg

Germany
20246

Study participating centre
Universitatsklinikum Schleswig-Holstein
Arnold Heller Straße 3,
Klinik für Innere Medizin I,
Kiel
Germany
24105

Study participating centre
Charité - Universitätsmedizin Berlin
Augustenburger Platz 1
Berlin
Germany
13353

Study participating centre
Robert Bosch Krankenhaus
Auerbachstrasse 112,
Stuttgart
Germany
70376

Study participating centre
Klinikum rechts der Isar der Technischen Universität München
Ismaninger Str. 22,
II. Medizinische Klinik und Poliklinik der TU München,München,
Bayern
Germany
81675

Study participating centre
Klinikum Schwabing
Kölner Platz 1, München
Bayern
Germany
80804

Study participating centre
Fondazione IRCCS
Policlinico San Matteo di Pavia, Viale Golgi 19,
UOC malattie Infettive I
Pavia
Italy
27100

Study participating centre
Ospedale San Raffaele S.r.l. – PPDS
Via Olgettina 60, Isituto Scientifico Universitario San Raffaele,Milano
Italy
20132

Study participating centre
ASST degli Spedali Civili di Brescia - Spedali Civili di Brescia
Pazzale Spedali Civili 1,U.O. di Malattie Infettive, Brescia
Italy
25123

Study participating centre
Azienda Ospedaliera Di Padova
Via Giustiniani 2,
Unità Operativa Malattie Infettive E Tropicali,
Padova,Veneto
Italy
35128

Study participating centre
Ospedale Guglielmo Da Saliceto
Via Taverna, 49
Piacenza, Emilia-Romagna
Italy
29100

Study participating centre
Comprensorio Amedeo Di Savoia Birago Di Vische
Corso Svizzera 164,

Torino,Piemonte
Italy
10149

Study participating centre
ASST Fatebenefratelli Sacco - Ospedale Luigi Sacco
Via Giovanni Battista Grassi, 74,
Dipartimento di Scienze Biomediche e Cliniche L. Sacco,MilanoLombardia
Italy
20157

Study participating centre
Fondazione IRCCS Cà Granda Ospedale Maggiore Policlinico
Via Francesco Sforza 35,
Milano,Lombardia
Italy
20122

Study participating centre
Azienda Ospedaliero Universitaria di Parma
Via Gramsci 14,
Parma
Italy
43100

Study participating centre
Istituto Nazionale Malattie Infettive Lazzaro Spallanzani IRCCS
Via Portuense 292
Roma
Italy
00149

Study participating centre
ASST di Cremona - Azienda Socio Sanitaria
Territoriale di Cremona,
Viale Concordia 1,
Cremona,Lombardia
Italy
26100

Study participating centre
ASST Papa Giovanni XXIII - Azienda Ospedaliera Papa
Giovanni XXIII,Piazza OMS 1,Bergamo
Italy
24127

Study participating centre
Academisch Medisch Centrum Amsterdam
Meibergdreef 9,
Amsterdam, Noord-Holland
Netherlands
1105 AZ

Study participating centre
Erasmus MC
Dr. Molewaterplein 230,
Rotterdam
Netherlands
3015GD

Study participating centre
Leids Universitair Medisch Centrum
Albinusdreef 2,
Leiden
Netherlands
2333 ZA

Study participating centre
Hospital Universitario A Coruña
As Xubias, 84,
A Coruña
Spain
15006

Study participating centre
Hospital Universitario La Paz – PPDS
Paseo de la Castellana 261, Madrid
Spain
28046

Study participating centre
Hospital Universitario de Bellvitge
Feixa Llarga s/n,
L'Hospitalet de Llobregat,
Barcelona
Spain
8907

Study participating centre
Hospital Regional Universitario de Malaga – Hospital General
Avda. Carlos Haya, s/n,
Servicio de Enfermedades Infecciosas,Malaga
Spain
29010

Study participating centre
Hospital Universitari i Politecnic La Fe de Valencia
Avenida Fernado Abril Martorell, 106,
Valencia
Spain
46026

Study participating centre
Hospital Universitario Virgen del Rocio – PPDS
Avenida Manuel Siurot s/n, Sevilla
Spain
41013

Study participating centre
Hospital Universitario Vall d'Hebrón – PPDS
Passeig de la Vall d'Hebron, 119,
Barcelona
Spain
8035

Study participating centre
Hospital Universitario de Cruces
Cruces Plaza, S/N,
Unidad enfermedades infecciosas,Barakaldo

Spain
48903

Study participating centre
Hospital Universitario Fundacion Jimenez Diaz
Av. Reyes Católicos 2,
Madrid
Spain
28040

Study participating centre
Hospital Universitario 12 de Octubre
Avenida de Andalucía s/n,
Madrid
Spain
28041

Study participating centre
Hospital Clinic de Barcelona
C/ Villarroel 170
Barcelona
Spain
08036

Study participating centre
Hospital Universitario Ramon y Cajal
Ctra. de Colmenar, Km. 9,100, Madrid
Spain
28034

Study participating centre
Hospital Universitario Principe de Asturias
Carretera de Alcala Meco s/n, Madrid
Spain
28805

Study participating centre
Karolinska University Hospital
Hälsovägen,

Stockholm
Sweden
SE-141 86

Study participating centre
Sahlgrenska Universitetssjukhuset
SE-41685, Göteborg,
Vastra Gotalands lan
Sweden
41685

Study participating centre
Skånes Universitetssjukhus Malmö
Ruth Lundskogs gata 3, Infektionskliniken,
Malmö
Sweden
SE-20502

Study participating centre
Ospedale Regionale Lugano Civico
Via Tesserete 46, Lugano,
Ticino (it),
Switzerland
6900

Study participating centre
Hopitaux Universitaires de Geneve (HUG),
4 Rue Gabrielle Perret-Gentil, Geneve
Switzerland
1205

Study participating centre
Universitätsspital Zürich
Rämistrasse 100,
Klinik für Infektiologie und Spitalhygiene,
Zürich
Switzerland
8091

Study participating centre
Manchester Royal Infirmary – PPDS
Oxford Road Campus
Manchester Foundation Trust Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Royal Free London NHS Foundation Trust
17 Lyndhurst Gardens,
Hampstead
London
United Kingdom
NW3 5NU

Study participating centre
University College London Hospitals (UCLH)
235 Euston Road
London
United Kingdom
NW1 2BU

Study participating centre
Derriford Hospital
Derriford Road
Crownhill
Plymouth
United Kingdom
PL6 8DH

Study participating centre
Royal Hallamshire Hospital
Glossop Road,
Sheffield
United Kingdom
S10 2JF

Study participating centre
St Mary's Hospital
Praed Street

London
United Kingdom
W2 1NY

Study participating centre
Queen Elizabeth University Hospital – PPDS
1345 Govan Road,
Glasgow
United Kingdom
G51 4TF

Study participating centre
Royal Lancaster Infirmary
-
Lancaster
United Kingdom
LA1 4RP

Study participating centre
Castle Hill Hospital
Castle Road
Cottingham
United Kingdom
HU16 5JQ

Study participating centre
King's College Hospital NHS Foundation Trust
King's College Hospital
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
Royal Liverpool University Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP

Study participating centre
North Manchester General Hospital – PPDS
Delaunays Road,
Crumpsall
Manchester
United Kingdom
M8 5RB

Study participating centre
Royal Infirmary of Edinburgh – PPDS
51 Little France Crescent
Edinburgh
United Kingdom
EH16 4SA

Study participating centre
Northwick Park Hospital
Watford Road
Harrow
London
United Kingdom
HA1 3UJ

Study participating centre
Icahn School of Medicine at Mount Sinai
17 East 102nd Street,
8th Floor, New York
United States of America
10029

Study participating centre
Mount Sinai Beth Israel
350 East 17th Street, 3rd floor, New York
United States of America
1003

Study participating centre

Mount Sinai West
1000 10th Avenue, Suite 2T, New York, NY
United States of America
10019

Study participating centre
Mount Sinai Morningside
440 West 114th Street, 6th floor, New York, NY
United States of America
10025

Study participating centre
St Joseph Hospital – Eureka
2700 Dolbeer Street,Eureka,
California
United States of America
95501

Study participating centre
Kadlec Regional Medical Center
888 Swift Boulevard, Richland,
Washington
United States of America
99352

Study participating centre
Jamaica Hospital Medical Center
800 Van Wyck Expressway,Jamaica,
New York
United States of America
11418

Study participating centre
Mission Hospital
27700 Medical Center Road, Mission Viejo,
California
United States of America
92691

Study participating centre
Hennepin Healthcare Research Institute
701 Park Avenue,
Minneapolis, Minnesota
United States of America
55415

Study participating centre
Hackensack University Medical Center
30 Prospect Avenue,
Hackensack,
New Jersey
United States of America
7601

Study participating centre
Henry Ford Hospital
2799 West Grand Blvd,
Detroit, Michigan
United States of America
48202

Study participating centre
James J Peters Veterans Administration Medical Center – NAVREF
130 West Kingsbridge Road, Bronx, New York
United States of America
10468

Study participating centre
St.Joseph Hospital – Orange
1100 West Stewart Drive,
Orange,California
United States of America
92868

Study participating centre
University of Colorado
4200 East 9th Avenue,
Denver, Colorado
United States of America
80262

Study participating centre
Providence Saint Patrick Hospital
500 West Broadway, Missoula,
Montana
United States of America
59802

Study participating centre
Inland Northwest Research
910 West 5th Avenue,
Suite500,Spokane,Washington
United States of America
99204

Study participating centre
Temple University Hospital
3401 North Broad Street ,Philadelphia,
Pennsylvania
United States of America
19140

Study participating centre
Hospital of the University of Pennsylvania
3400 Spruce Street
Philadelphia, PA
United States of America
19104

Study participating centre
Hospital of the University of Pennsylvania
3400 Spruce Street,
Philadelphia, Pennsylvania
United States of America
19104

Study participating centre
Providence Regional Medical Center Everett
1321, Colby Avenue,

Office B3-018,
Everett, Washington,
United States of America
98122

Study participating centre
Long Island Jewish Medical Center
270-05 76th Aven
New Hyde Park, NY
United States of America
11040

Study participating centre
Northwell Health,
300 Community Drive,
Manhasset, New York
United States of America
11030

Study participating centre
Mills Peninsula Medical Center
1501 Trousdale Drive, Burlingame,
California
United States of America
94010

Study participating centre
Tulane University School of Medicine
1415 Tulane Avenue,
New Orleans,
Louisiana
United States of America
70112

Study participating centre
Swedish Medical Center
747 Broadway,
Seattle, Washington,
United States of America
98122

Study participating centre
Baylor University Medical Center
3500 Gaston Ave,
Dallas, Texas
United States of America
75246

Study participating centre
Baylor Scott & White All Saints Medical Center
1400 8th Ave
Fort Worth, TX
United States of America
76104

Study participating centre
Baylor Scott & White Medical Center -Temple
2401 S 31st St
Temple, TX
United States of America
76508

Study participating centre
Sutter Santa Rosa Regional Hospital
30 Mark West Springs Rd,
Santa Rosa, California
United States of America
95403

Study participating centre
Houston Methodist Hospital
6565 Fannin Street, TX Medical Flagship, Houston,
Texas
United States of America
77030

Study participating centre
Indiana University School of Medicine-Indianapolis
545 Barnhill Drive,
Emerson Hall,

Suite 421, Indianapolis,
Indiana
United States of America
46077

Study participating centre
Rose Medical Center
4567 East 9th Avenue,
Denver, Colorado
United States of America
80220

Study participating centre
Providence St. John's Health Center
2121 Santa Monica Blvd,
1st Floor, Santa Monica,
California
United States of America
90404

Study participating centre
Prisma Health–Midlands
5 Richland Medical Park Drive, Columbia,
South Carolina
United States of America
29203

Study participating centre
Prisma Health-Greenville Memorial Hospital
701 Grove Rd
Greenville, SC
United States of America
29605

Study participating centre
University Hospitals Cleveland Medical Center
11100 Euclid Ave,
Cleveland, Ohio
United States of America
44106

Study participating centre
John H. Stroger, Jr. Hospital of Cook County
1901 West Harrison Street, Chicago,
Illinois
United States of America
60612

Study participating centre
University of Utah – PPDS
50 N Medical Drive,
Salt Lake City, Utah
United States of America
84132

Study participating centre
University Of Iowa Hospitals And Clinics
200 Hawkins Drive,
Iowa City, Iowa
United States of America
52242

Study participating centre
UT Southwestern Medical Center–ID Clinical Research
1936 Amelia Court
2nd Floor
Dallas, TX
United States of America
75235

Study participating centre
UT Southwestern Medical Center–ID Clinical Reseach
1936 Amelia Court
2nd Floor
Dallas, TX
United States of America
75235

Study participating centre

Holy Cross Hospital
1500 Forest Glen Road,
Silver Spring, Maryland
United States of America
20910

Study participating centre
Franciscan Health System Research Center
1708 South Yakima Avenue, Suite 300,
Tacoma, Washington
United States of America
98405

Study participating centre
University of Michigan
1500 East Medical Center Drive, Ann Arbor,
Michigan
United States of America
48109

Study participating centre
Inova Fairfax Hospital
3300 Gallows Road,
Falls Church, Virginia
United States of America
22042

Study participating centre
Sutter Medical Center Sacramento
2825 Capitol Avenue,
Sacramento, California
United States of America
95816

Study participating centre
Sutter Roseville Medical Center
One Medical Plaza
Roseville, CA
United States of America
95661

Study participating centre
Jacobi Medical Center
1400 Pelham Parkway South, Bronx, New York
United States of America
10461

Study participating centre
California Pacific Medical Center
1101 Van Ness Avenue, San Francisco,
California
United States of America
94109

Study participating centre
Virginia Mason Medical Center
1100 9th Avenue,
Seattle, Washington
United States of America
98101

Study participating centre
Tacoma General Hospital
315 Martin Luther King Jr Way ,Tacoma, Washington
United States of America
98405

Study participating centre
Liver Institute at Methodist Dallas
1411 North Beckley Avenue, Pavillion III,
Suite 268, Dallas,
Texas
United States of America
75203

Study participating centre
New York Presbyterian Hospital - Weill-Cornell
525 East 68th Street,

New York
United States of America
10065

Study participating centre
Brigham and Womens Hospital
75 Francis Street, Division of Infectious Disease,
Brigham and Women's Hospital, Boston, Massachusetts
United States of America
2115

Study participating centre
Alta Bates Summit Medical Center
2450 Ashby Avenue,
Berkeley, California
United States of America
94705

Study participating centre
Virginia Hospital Center
1701 North George Mason Drive,
Arlington, Virginia
United States of America
22205

Study participating centre
Kaiser Permanente
Skyline Medical Office
1375 East 20th Avenue
Denver, CO
United States of America
80204

Study participating centre
Kaiser Permanente Center For Health Research
3800 North Interstate Avenue, Portland,
Oregon
United States of America
97227

Study participating centre
Kiaser Westside Medical Center
2875 NW Stucki Ave., Hillsboro, OR
United States of America
97124

Study participating centre
University of Chicago
5841 S. Maryland Ave.,
Chicago, Illinois
United States of America
60637

Study participating centre
Somerset Medical Center
110 Rehill Avenue,
Somerville, New Jersey
United States of America
8876

Study participating centre
Robert Wood Johnson University Hospital New Brunswick
1 RWJ Place
New Brunswick, NJ
United States of America
08901

Study participating centre
Newark Beth Isreael Medical Center
201 Lyons Avenue
Newark, NJ
United States of America
07112

Study participating centre
Danbury Hospital
24 Hospital Avenue,
Danbury, Connecticut
Uruguay
6810

Study participating centre
Columbia University Medical Center
622 W 168th St,
PH E101, New York
United States of America
10032

Study participating centre
Yale-New Haven Hospital
20 York St, New Haven,
Connecticut
United States of America
06510-3220

Study participating centre
Tufts Medical Center – PPDS
800 Washington Street, Boston,
Massachusetts
United States of America
2111

Study participating centre
Providence Saint Vincent's Medical Center
9205 Southwest Barnes Road, Portland,
Oregon
United States of America
97225

Study participating centre
St Joseph's Regional Medical Center
703 Main Street,
Paterson, New Jersey
United States of America
7503

Study participating centre
Mayo Clinic – PPDS
200 First Street Southwest, Rochester,

Minnesota
United States of America
55905

Study participating centre
Hoag Memorial Hospital Presbyterian
One Hoag Drive, Newport Beach,
California,
United States of America
92663

Study participating centre
Virginia Commonwealth University
1250 East Marshall Street,
Richmond, Virginia
United States of America
23298

Study participating centre
Maine Medical Center
22 Bramhall Street,
Portland, Maine
United States of America
4102

Study participating centre
Eden Medical Center
20103 Lake Chabot Road,
Castro Valley,
California
United States of America
94546

Study participating centre
Rush University Medical Center
1653 W. Congress Parkway, Chicago,
Illinois
United States of America
60612

Study participating centre
Kaiser Permanente Oakland Medical Center
3600 Broadway,
Oakland, California
United States of America
94611

Study participating centre
Kaiser Permanente San Francisco Medical Center
2425 Geary Blvd. San Francisco, CA
United States of America
94115

Study participating centre
Kaiser Permanente South San Francisco Medical Center
1200 El Camino Real, San Francisco, CA
United States of America
94080

Study participating centre
Kaiser Permanente San Jose Medical Center
250 Hospital Parkway, San Jose, CA
United States of America
95119

Study participating centre
Kaiser Permanente San Leandro Medical Center
2500 Merced Street San Leandro, CA
United States of America
94577

Study participating centre
Kaiser Permanente Santa Clara
700 Lawrence Expressway, Santa Clara, CA
United States of America
95051

Study participating centre

Providence St Peter Hospital
, 413 Lilly Road Northeast, Olympia,
Washington
United States of America
98506

Study participating centre
Beth Israel Deaconess Medical Center
330 Brookline Avenue,
Boston, Massachusetts
United States of America
2215

Study participating centre
Stanford University School of Medicine
300 Pasteur Drive,
Stanford, California
United States of America
94305

Study participating centre
Miriam Hospital
164 Summitt Avenue,
Providence,
Rhode Island
United States of America
2906

Study participating centre
Woodland Hills Medical Center
5601 De Soto Avenue, Woodland Hills, CA
United States of America
91365

Study participating centre
Ontario Medical Center
2295 S. Vineyard Avenue
Ontario, CA
United States of America
91761

Study participating centre
San Diego Medical Center
9455 Clairemont Mesa Blvd
San Diego, CA
United States of America
92123

Study participating centre
Zion Medical Center
4647 Zion Avenue, San Diego, CA
United States of America
92120

Study participating centre
Downey Medical Center
9333 Imperial Highway
Downey, CA
United States of America
90241

Study participating centre
Riverside Medical Center
10800 Magnolia Avenue
Riverside, CA
United States of America
92505

Study participating centre
Kaiser Permanente Los Angeles Medical Center
4867 West Sunset Boulevard, Los Angeles, California
United States of America
90027

Study participating centre
Orange County Anaheim Medical Center
3440 E. La. Palma Avenue
Anaheim, CA
United States of America
92806

Study participating centre
West Los Angeles Medical Center
6041 Cadillac Avenue, Los Angeles, CA
United States of America
90034

Study participating centre
Moreno Valley Medical Center
27300 Iris Avenue
Moreno Valley, CA
United States of America
92555

Study participating centre
Fontana Medical Center
9961 Sierra Avenue
Fontana, CA
United States of America
92335

Study participating centre
Panorama City Medical Center
13651 Willard Street
Panorama City, CA
United States of America
91402

Study participating centre
South Bay Medical Center
25825 S. Vermont Avenue
Harbor City, CA
United States of America
90710

Study participating centre
Duke University Medical Center
2301 Erwin Road,
Durham, North Carolina

United States of America
27710

Study participating centre
Dartmouth-Hitchcock Medical Center
1 Medical Center Drive,
Lebanon, New Hampshire
United States of America
3766

Sponsor information

Organisation
Gilead Sciences (United States)

ROR
https://ror.org/056546b03

Funder(s)

Funder type
Industry

Funder Name
Gilead Sciences

Alternative Name(s)
Gilead, Gilead Sciences, Inc., Oligogen

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. Gilead Sciences shares anonymized individual patient data upon request or as required by law or regulation with qualified external researchers based on submitted curriculum vitae and reflecting non conflict of interest. The request proposal must also include a statistician. Approval of such requests is at Gilead Science's discretion and is dependent on the nature of the request, the merit of the research proposed, the availability of the data, and the intended use of the data. Data requests should be sent to datarequest@gilead.com . Data will become available 18 months after study completion and will be accessible in a secured external environment. More information on Gilead's data sharing policy can be found here: https://www.gilead.com/science-and-medicine/research/clinical-trials-transparency-and-data-sharing-policy

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	27/05/2020	29/10/2020	Yes	No
Basic results				No	No
HRA research summary			28/06/2023	No	No