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Executive Summary

CG's Scientific and Regulatory Group is a tailored group of services that facilitates and manages independent expert committees, including Endpoint Adjudication Committees and Data Monitoring Committees. In addition to the clients we serve, WCG also maintains its own network, a "Virtual Faculty", of over 900 expert physicians and statisticians that can serve as a source of committee members.

WCG leverages these strong relationships with academia in order to enhance our expert committee solutions for our clients. We recruit from esteemed institutions worldwide to ensure that a wide variety of backgrounds, geographic locations, and therapeutic specialties are represented within our network.

Each member of our virtual faculty has been pre-vetted for their committee experience, performance, responsiveness, therapeutic expertise and technical aptitude. WCG's Medical-Regulatory Consultant MD personally interviews each member before new projects are contracted to ensure understanding and agreement to expectations.

WCG collaborates with our clients to determine any geographic, scientific expertise, or regulatory needs that would comprise the ideal member profiles for any new project. WCG will recruit the appropriate members, perform conflict-of-interest vetting, and then present CVs and rates for sponsor approval. Members are always mutually approved between WCG and the project sponsor.

WCG performs annual updates to our member database to ensure that we have accurate information on the members that could potentially serve on expert committees for client projects. In addition to regular member communications, formal surveys are issued annually to collect key information about specific areas of expertise. The following table provides a high-level member demographics snapshot of WCG's current network of global experts.

Summary Metrics of WCG's Network of Experts



963 Members in Network



350 Academic Institutions represented in Network



25 Therapeutic Specialties represented



85 Sub-Specialties represented



904 Clinicians in Network



58 Statisticians in Network



70% of Network with Direct Regulatory Agency Experience

Member Characteristics

Through management of hundreds of committee projects, WCG has gained significant experience and insight into the ideal member characteristics that are needed to comprise different types of committees. Suggested criteria for EAC and DMC members are as follows:

EAC Member Criteria:

 Recognized expertise in the area for which member is selected (typically therapeutic area), as evidenced by academic appointment or other teaching activities, relevant publications or competence; may be demonstrated by active clinical practice in the area of interest

- The ability to accurately review patientcentered records and tabular data
- The ability to design and adhere to programmatic rules which define clinical endpoints
- Understanding of the role of an EAC within the context of the regulatory approval process
- Able to understand the evidence necessary to support Charter definitions in the adjudication process as evidenced by academic training or fellowship in a professional society
- Willingness to perform adjudication tasks in a timely fashion on an ongoing basis
- Comfort making adjudication decisions using electronic media
- Able to summarize the case and rationale for the decision in a concise English narrative

DMC Member Criteria:

- Ability to interpret clinical trial data analyses
- Understanding of the role of a DMC within the context of the regulatory approval process
- Recognized professional accomplishment in the area for which member is selected (typically therapeutic area or scientific field of a presumptive safety concern);

- evidence includes board certifications, status as fellow in an academic society, relevant publications, academic appointment, etc.
- Experience in clinical trials of a similar scope as the proposed DMC project, evidenced by participation as a principal investigator or an author role in clinical trial research publication
- Experience in clinical practice
- Willing, available and able to meet periodically over the course of the trial
- Willing to meet emergently in the case of a potential trial modification

Committee Chair Suggested Requirements:

- Must meet all requirements listed above for the appropriate type of committee
- Prior experience as a member on at least2 previous committees
- Knowledgeable about the regulatory environment related to drug development
- Able to manage other clinical experts as evidenced by previous DMC, EAC or trial committee chairmanships or leadership roles at academic or professional venues
- Agreement with the sponsor about the role of the committee and the roles of the chairman

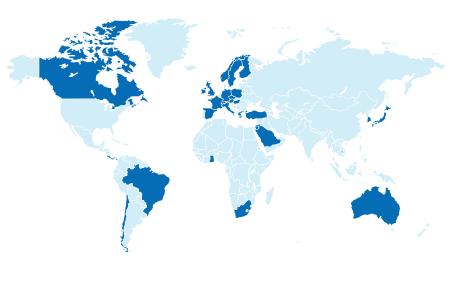
Member Geographic Distribution

WCG's Virtual Faculty includes numerous members from around the world. Due to the global nature of many expert committee projects, WCG continues to build relationships in numerous foreign countries to ensure appropriate geographic representation whenever necessary.



Member Sub-Specialties

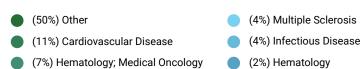
Argentina	Ghana	Saudi Arabia
Australia	Greece	Singapore
Austria	Hungary	South Africa
Belgium	Ireland	South Korea
Brazil	Israel	Spain
Canada	Italy	Sweden
Czech Republic	Japan	Switzerland
Denmark	Jordan	The Netherlands
inland	Norway	Turkey
France	Panama	United Kingdom
Germany	Poland	



Member Therapeutic Specialties

WCG's Virtual Faculty members have supported projects in all therapeutic areas across the clinical development spectrum. These are the current therapeutic specialties and sub-specialties represented below. Additional areas of expertise can be sourced rapidly through WCG's established channels upon client request.



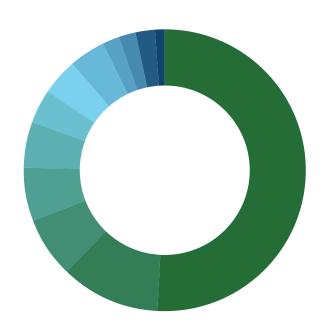


(6%) Gastroenterology

Member Sub-Specialties

(5%) Medical Oncology

(4%) Critical Care; Pulmonary Disease (1%) Vascular Neurology



(2%) Pulmonary Disease

(2%) Rheumatology

Member Therapeutic Sub-Specialties

- Addiction Psychiatry
- Adolescent Medicine; Endocrinology Diabetes and Metabolism
- Cardiovascular Disease
- Cardiovascular Disease; Cardiac Electrophysiology
- Cardiovascular Disease; Critical Care Medicine
- Cardiovascular Disease; Heart Failure & Transplant Cardiology
- Cardiovascular Disease; Interventional Cardiology
- Cardiovascular Disease; Interventional Cardiology; Pediatric Cardiology
- Cardiovascular Disease; Medical Oncology
- Child Neurology
- Child Neurology; Multiple Sclerosis
- Child Neurology; Sleep Medicine
- Clinical Cardiac Electrophysiology
- Clinical Cardiac Electrophysiology; Interventional Cardiology
- Clinical Cardiac Electrophysiology; Pediatric Cardiology
- Clinical Genetics (MD)
- Clinical Genetics (MD); Endocrinology Diabetes and Metabolism
- Clinical Neurophysiology
- Critical Care Medicine
- Critical Care Medicine; Infectious Disease;

Pulmonary Disease

- · Critical Care Medicine; Pain Medicine
- Critical Care Medicine; Pulmonary Disease
- Critical Care Medicine; Pulmonary Disease;
 Sleep Medicine
- Dermatopathology
- Diagnostic Radiology
- Diagnostic Radiology; Neuroradiology
- Endocrinology Diabetes and Metabolism
- Endocrinology Diabetes and Metabolism;
 Geriatric Medicine
- Gastroenterology
- Gastroenterology; Hematology; Medical Oncology
- Gastroenterology; Infectious Disease
- Gastroenterology; Medical Oncology
- Gastroenterology; Transplant Hepatology
- · Geriatric Medicine
- Gynecologic Oncology
- Gynecologic Oncology; Medical Oncology
- Hematology
- Hematology; Infectious Disease; Medical Oncology
- Hematology; Interventional Cardiology
- Hematology; Medical Oncology
- Hematology; Medical Oncology; Molecular Genetic

- Pathology
- · Infectious Disease
- Infectious Disease; Internal Medicine-Critical Care
- Infectious Disease; Pediatric Infectious Diseases
- Interventional & Diagnostic Radiology
- Interventional & Diagnostic Radiology; Vascular Surgery
- Interventional Cardiology
- Interventional Cardiology; Pulmonary Disease
- · Maternal and Fetal Medicine
- Medical Oncology
- Multiple Sclerosis
- Neonatal-Perinatal Medicine
- Nephrology
- Neuromuscular Medicine
- Neuroradiology
- Neurosurgical Ophthalmology
- Orthopedic Sports Medicine
- Pain Medicine
- Pediatric Anesthesiology
- Pediatric Cardiology
- Pediatric Critical Care Medicine
- Pediatric Emergency Medicine
- Pediatric Gastroenterology
- Pediatric Transplant Hepatology
- Pediatric Hematology-Oncology

- Pediatric Infectious Diseases
- Pediatric Nephrology
- Pediatric Ophthalmology
- Pediatric Pulmonology
- Pediatric Pulmonology; Sleep Medicine
- Pediatric Surgery
- Pediatric Surgery; Pediatric Urology
- Pediatric Urology
- Plastic Surgery- Head and Neck
- Pulmonary Disease
- · Pulmonary Disease; Sleep Medicine
- Radiation Oncology
- Rheumatology
- Sleep Medicine
- · Sports Medicine
- Surgical Critical Care
- Vascular and Interventional Radiology
- Vascular Neurology
- Vascular Surgery

Member Institutions

- A.I. DuPont Hospital for Children
- Hospital Clinic I Provincial
- Royal Victoria Hospital
- University of Copenhagen
- · Aarhus University Hospital
- Hospital Del Niño
- · Ruhr University/ St. Josef-Hospital
- University of Denver
- · Abington Jefferson Health
- Hospital Del Niño
- · Ruprecht-Karls-Universität Heidelberg
- University of Dundee
- Academisch Medisch Centrum
- Hospital for Sick Children
- Rush University Medical Center
- University of Edinburgh
- Aichi Cancer Center
- Hospital General Universitario
- Rutgers University
- University of Essen
- · Alameda Health Partners
- Hospital General Universitario
- · Saint Luke's Mid America Heart
- University of Florence Medical School
- Anova Health Institute
- Hospital of the University of Munich
- Samsung Medical Center
- · University of Florida
- · Aristotle University of Thessaloniki
- Hospital of the University of Pli
- Seattle Children's Hospital
- University of Freiburg Medical Center
- Asklepios Hospitals Schildautal
- · Hospital of the University of
- Sheba Medical Center
- University of Genoa
- Asklepios Klinikum Uckermark,
- Hospital Universitario Miguel Servet
- St Mary's Hospital Medical School
- University of Ghana

- Augusta University Medical Center
- Hospital Universitario Miguel Servet
- St. Anthony Medical Center
- · University of Glasgow
- Banner Health
- Hospital Universitario y Politecnico La Fe
- St. Antonius Hospital Nieuwegein/ Utrecht and Division Heart
- University of Göttingen Medical School
- Bay West Endocrinology Associates
- Hospitalier Universitaire de Sherbrooke
- St. Boniface General Hospital
- · University of Heidelberg
- Baylor College of Medicine
- · Houston Methodist
- St. Elisabeth Hospital
- University of Innsbruck
- BC Cancer Agency
- · Houston Methodist
- St. Francis Hospital
- University of Insubria, Varese
- · Beth Israel Deaconess Medical
- · Humanitas Research Hospital
- St. George's University of London
- · University of Iowa
- Beth Israel Medical Center,
 Comprehensive Cancer Center
- Humanitas Research Hospital
- St. Louis Children's Hospital
- University of Jordan
- BHF Glasgow Cardiovascular
- Icahn School of Medicine at Mount
- St. Michael's Hospital
- · University of Kansas Medical Center
- Bichat University Hospital
- Indiana University Hospital
- St. Thomas' Hospital
- University of Liverpool
- · Bispebjerg Hospital, Copenhagen
- Indiana University School of Medicine

- Stanford University
- · University of Manchester
- Borsod Central Teaching County Hospital
- IRCCS Policlinico San Donato
- Steward St. Elizabeth's Medical Center
- University of Marburg
- Boston Children's Hospital
- Istanbul University
- Sungkyunkwan University School of Mdii
- University of Maryland
- Boston University
- Jacobs School of Medicine and Biomedical Sciences
- Sunnybrook Health Sciences Center
- University of Massachusetts School of Medicine
- · Bridgeport Hospital, Yale New
- Jefferson Health-Sidney Kimmel
- · Sutter Pacific Medical Foundation
- University of Medicine and Dentistry
- Brigham and Women's Hospital
- Jennersvile Regional Hospital
- Temple University School of Medicine
- · University of Melbourne
- · Bristol Children's Hospital
- Johannes Gutenberg University
- Texas Cardiac Arrhythmia Institute
- · University of Miami Health System
- Brown University
- Johns Hopkins University
- The Alexandra and Steven Cohen
- University of Michigan
- Buffalo General Medical Center
- Johns Hopkins University School of Medicine
- The Children's Hospital of Philadelphia
- · University of Minnesota
- · Cardiff University School of

- Kantonsspital St. Gallen
- · The Cleveland Clinic Foundation
- University of Mississippi Medical
- Case Western University, School of Medicine
- Katholieke Universiteit Leuven
- · The George Washington University
- · University of Murcia
- Catholic University in Rome
- · Kerckoff Heart and Thorax Center
- · The Johns Hopkins Hospital
- University of Nebraska Medical Center
- · Cedars-Sinai Medical Center
- · Kessler Institute for Rehabilitation
- The Methodist Hospital
- University of New York
- · Changi General Hospital
- KfH Kidney Center
- The Monter Cancer Center
- University of Nice Medical Center
- · Charité Universitätsmedizin Berlin
- King Faisal Specialist Hospital and
- · The University of Alabama at
- University of North Carolina
- · Charles University
- · King's College, Medical Center
- · The University of Arizona College of
- · University of Nottingham
- Chelsea & Westminster Hospital
- Kingston General Hospital
- The University of Chicago
- University of Oregon
- CHI Bergan Mercy Medical Center
- · Klinikum Frankfurt-Hochst
- The University of Manchester
- University of Pennsylvania
- Children's Hospital Colorado
- Klinikum Koln-Merheim University
- The University of Texas Southwestern
- University of Perugia
- Children's Hospital Helsinki

- Langley Air Force Base Hospital
- The Urological Institute of
- University of Pisa
- · Children's Hospital Oakland
- · Lankenau Hospital, Main Line Health
- Thomas Jefferson University
- University of Pittsburgh
- · Children's Hospital of Michigan
- · Le Bonheur Children's Hospital
- Thomas Jefferson University Hospital
- University of Queensland
- Children's Hospital of Philadelphia
- Leeds Institute of Cancer & Pathology
- Toulouse University Hospital
- University of Regensburg
- · Children's National Medical Center
- · Leeds Institute of Rheumatic
- Trinity Medical Associates
- University of Rochester Medical
- · Christiana Care Health System
- London School of Hygiene & Tropical
- · Tufts University School of Medicine
- · University of Rouen
- · CHU UCL Namur
- Loyola University Medical Center
- · Tulane University School of Medicine
- · University of Saarland
- · Cincinnati Children's Hospital
- Ludwig-Maximilians-University (LMU)
- · UAB School of Public Health
- University of South Carolina
- Cleveland Clinic
- · Lung Specialists of Merrimack Valley
- UCLA
- University of Southern California (USC)
- Clinique de Genolier
- · Lurie Children's Hospital of Chicago
- Ulm University
- University of Southern Denmark
- · Cliniques universitaires Saint-Luc

- Maimonides Medical Center
- United Lincolnshire Hospitals NHS Trust University of Tex
- CMU College of Medicine
- Main Line Health Care
- Universitaire de Genève
- · University of Texas Southwestern
- Cochin Hospital
- Maine Medical Center
- Universität Ulm, Neurologische Klinik
- · University of the Witwatersrand
- · Columbia University
- · Manchester University
- Universitätsklinikum Schleswig-Holstein
- University of Torino
- Copenhagen University Hospital
- Marienkrankenhaus
- University Children's Hospital Zurich
- University of Toronto
- Cornell University
- Maryland Psychiatric Research Center
- University Clinical Hospital of Valladolid
- University of Ulm
- Dana-Farber Cancer Institute
- · Massachusetts General Hospital
- University College Galway Hospitals
- University of Utah
- Dresden University of Technology
- · Mayo Clinic
- · University College London Institute
- · University of Vermont
- · Duke University Medical Center
- McMaster University
- · University Heart Center Hamburg-
- University of Virginia
- Ealing Hospital
- MD Anderson Cancer Center
- University Hospital Bern
- University of Warwick
- Emma Children's Hospital AMC

- Medical College of Wisconsin
- University Hospital Dresden
- · University of Washington
- · Emory University
- Medstar Harbor Hospital
- University Hospital Essen
- University of Wisconsin
- Ephrata Community Hospital
- Medstar Washington Hospital Center
- · University Hospital Giessen and
- · University of Yamanashi
- · Erasmus University Rotterdam
- Memorial Hospital of Rhode Island
- University Hospital Henri Mondor
- · University of Zurich
- Federation de Neurologie, Hôpital
- Memorial Sloan-Kettering Cancer
- University Hospital Maastricht
- USC Keck Medical Center
- · Fox Chase Cancer Center
- Mercy Catholic Medical Center
- University Hospital of Lausanne (CHUV)
- UT Southwestern Medical Center
- Fred Hutchinson Cancer Research Center
- · MetroHealth Medical Center
- University Hospital of North Norway
- Utrecht University Medical Center
- Freeman Hospital
- Moffitt Cancer Center
- University Hospital Schleswig-Holstein
- · VA Medical Center
- Fukuoka University Hospital
- Monash University
- University Hospital, Christian-Albrechts- University Kiel
- Vall d'Hebron University Hospital
- GastroHealth and Miami Cancer
- · Montefiore Medical Center
- · University Hospitals Cleveland
- Vanderbilt University Medical Center

- Georgetown University Hospital
- Montefiore Unversity Hospital
- University Hospitals Leuven
- · Veterans Affairs Medical Center
- Georgetown University Medical Center
- · Mount Sinai School of Medicine
- · University Hospitals Leuven, Belgium
- Virginia Commonwealth University
- Glenfield Hospital, Department of
- Munich General Hospital
- University Medical Center Gottingen
- Virginia Mason
- · Gosford and Wyong Hospitals
- Murdoch Childrens Research Institute
- University Medical Center Groningen
- · Vituity, St Rose Hospitals
- Gustave Roussy Institute
- MUSC Health
- University Medical Centre Utrecht
- Vivantes Klinikum Neukölln
- Hahnemann University Hospital
- National Hospital for Neurology and Neurosurgery
- University of Alabama School of Medicine
- VU University Medical Center Amsterdam
- Hamilton General Hospital
- · National Pediatric Hospital
- · University of Alabama at Birmingham
- · Wake Forest School of Medicine
- · Hamilton Health Sciences-McMaster
- Nationwide Childrens Hospital
- University of Alberta
- · Washington State University
- Harvard Medical School
- · Neurologische Gemeinschaftspraxis
- University of Amsterdam
- · Weill Cornell Medicine
- · Haukeland University Hospital
- New Brunswick Heart Centre-Saint

- John Regional Hospital
- University of Arizona
- Western Michigan University
- Heidelberg University Medical Center
- New England Baptist Hospital
- University of Athens
- Western University
- Helsinki University Central Hospital
- New York Medical College
- · University of Birmingham
- Wilhelminen Cancer Research Institute
- Henry Ford Hospital
- Pierre and Marie Curie University
- · University of British Colombia
- Wroclaw Medical University
- Höhe Otto Wagner Hospital and Care Centre
- Pontifícia Universidade Católica do Rio Grande
- · University of Calgary
- Würzburg University Medical Center
- Hope Neurology, Baptist Hospital West
- · Queen's University of Belfast
- · University of California
- Yale University
- Hôpital Claude Huriez
- Rhode Island Hospital
- University of Cape Town
- · Zenter Research S.A.
- Hôpital Hautepierre CHU b
- · Rothman Institute
- University of Chicago
- Hôpital Henri Mondor
- Royal Brompton Hospital
- · University of Chieti
- Hôpital Henri Mondor
- · Royal London Hospital
- University of Cincinnati

WCG's Approach to Member Services

The WCG approach to member relationships is a vital part of our service offerings and mission. Our Member Services department is dedicated to the support of our global experts. We work to ensure that we provide our committee members with the most expeditious processes, software and support to allow them to perform at maximum capacity while focusing on their committee work.

WCG vigilantly monitors industry trends to ensure that our network is representative of the therapeutic areas in development. As clinical specialties are constantly evolving, WCG has dedicated recruitment processes in place to ensure that we can accommodate every client project that is brought to our attention. If we do not readily have a member with the necessary therapeutic expertise, it takes less than 4 weeks from contract signature with a sponsor to recruit, qualify and contract a new member.

Our relationship and contact with our expert members is nurtured throughout the lifecycle of not only the project but their tenure of membership in our virtual faculty. Our experts are regularly polled and contacted to ensure that WCG is providing them with the best service and partnership and to solicit feedback and suggestions for improving our processes, relationships and impact of the global research community. To the right are a few examples of member feedback we have received.

"The process is much more streamlined than other studies I work on – very efficient."

"The web-based system was a great surprise. Never imagined that it would be so useful."

"Really the best team I've worked with, and I've done a lot of adjudication work. Topnotch. I do not have anything negative to say."

"The WCG team is wonderful. I work on many committees and this is the best. Great job keeping things on track. Has strong understanding of adjudication."

"WCG has been great, as usual, about working with us and getting us what we need from the sites. The workload is very manageable."

"The WCG responsiveness is excellent, always polite and timely."

"I am very proud to be a member of the Adjudication Committee and I really thank you for the fantastic cooperation. I am very impressed by your expertise and your logistic handling of the studies."

"It's been fantastic working with WCG, and this is the best group of CEC members I've had the pleasure to work with."

"I greatly enjoy the process, the collaboration, and the opportunity to "get it right" for you, the trial, and the sponsor. Thanks for allowing me to be involved."



WCG is the world's leading provider of solutions that measurably improve the quality and efficiency of clinical research. Comprised of two segments, Ethical Review and Clinical Trials Solutions, WCG enables biopharmaceutical companies, CROs, and institutions to advance the delivery of new treatments and therapies to patients, while maintaining the highest standards of human participant protection.

For more information visit www.wcgclinical.com