CLINICAL**DEVICE**GROUP

CRO Capabilities from Clinical Device Group

A brief description of our services

It starts with a technology

You know your technology works, now it's time for a clinical trial. CDG is here to help. We have a unique business model: all professional work is sub-contracted to our spider-web of expert Network Staff Associates. Click http://www.nancystark.com/CDG_eBrochure.pdf for an Acrobat pdf copy of our brochure and business model.

Marketing needs determine indications for use

Meet Judi Bednarz

Next comes deciding which indication(s) you should pursue. CDG suggest's "easy claims first" but our marketing specialist, Judi Bednarz, can help you phrase your indications and claims to get the best play in the marketplace with the least burdensome requirements from FDA. "Work with the words", says Judi. We often ask her to assist in investigative site recruitment. With her knowledge of how to find people who know things, she is ideal for finding investigators with unusual skill-sets or hard-to-find subjects.

Biological Safety Assessments

Meet Dr. Dan McLain—Toxicologist

Investigational device safety is of primary consideration before any human exposure to a device. The animal biological safety tests and animal preclinical safety and performance experiments can be reviewed in the Investigator's Brochure or Report of Prior Investigations by device toxicologist Dr. Dan McLain. Dan's PhD in toxicology, status as a convener for ISO 10993-11, and years of experience in the medical device field give him high credentials for assessing the biocompatibility of a new technology or device, for preparing expert reports to include in regulatory submissions, or in answering questions you have received from FDA.

Clinical Evaluation Reports, Investigator's Brochures, Medical Writing

A Clinical Evaluation Report is a review of existing clinical and safety data to: a) determine there is already sufficient data to support your technology's safety and performance for its intended use, or b) justify the design of a clinical trial. We have a team of medical writers and information specialists who can prepare these essential reports for you.

Meet MEDIcept Inc—Medical Writers

F. David Rothkopf, founder and President of MEDIcept, has more than 20 years of professional strategic experience in the development, quality and regulatory control of medical devices. They offer engineering, quality, and regulatory consulting assistance to the medical device and blood plasma industry. MEDIcept's Todd Rhode and Joanne Fides have engineering and quality system backgrounds that give them an edge in technical writing for high-technology devices.

Meet Dr. Charles Hurwitz—Medical Writer

American-born and educated, Dr. Charles Hurwitz has a PhD in Biology. He earns his living as a medical writer, writing instruction manuals, manuscripts, and clinical evaluation reports. He has worked for several biotech companies and has prepared many 510(k) and CE submissions. Living in Israel gives him an advantage; he is closer to "Euro-think" than

most Americans.

Meet Sunny Worel—Information Specialist

Sunny Worel was a former medical librarian. She has a background in Biochemistry and Microbiology (from the University of Minnesota). Sunny worked on the laboratory side of clinical trials and made immunodiagnostic kits before getting her Master in Library Science. She has been in independent information specialist with skills in Embase, MedLine, and other biomedical searches for many years.

Meet Brian Hartman—Information Specialist

Mr Hartman holds a Masters Degree in Library Service, is proficient in Embase, MedLine and other biomedical database searches, and is highly comfortable in Access, Excel, HTML, and Visual Basic development. He brings a unique background in information management to his responsibilities as Information Specialist at CDG.

Regulatory professionals

Meet Kathleen Johnson—Pre-IDE meetings and regulatory strategies for devices

Kathleen has 12 years of experience in regulatory consulting. She is knowledgeable about the requirements for all classes of devices and has submitted many 510(k)s for both Class II and Class III devices, has experience with pre-IDE meetings and IDE submissions, and can prepare Regulatory assessments for potential investor presentations. She also has experience with Quality System Manual preparation as well as Quality System Audits.

Meet Dr. Gail Radcliffe—Strategies for IVD start-ups

Gail loves a challenge and focuses her practice on new and interesting technologies. Her education in molecular biology and virology give her strong credentials for helping diagnostic companies with complex new products. Gail has provided regulatory strategy for numerous diagnostic and biological devices, assessed market opportunities for new technologies, developed business models (CLIA vs. FDA) for novel biomarker IVDs, and has helped investor and university technical transfer offices determine the value of their IVD based intellectual property.

Meet Fabio De Pasquale

Living in British Columbia, Canada, Fabio De Pasquale has worked with several local and US companies helping them to bring their devices to the US, Canadian and European markets. His experience in quality assurance allows him to advise small companies on how to set up quality management systems. His expertise in regulatory affairs allows him to bring fresh ideas to wording indications for use so that the best regulatory pathway is an option.

Meed MEDIcept Inc—Regulatory Engineers

In addition to medical writing, David Rothkopf's group at MEDIcept is adept at developing regulatory submissions such as IDEs, 510(k)s, PMAs, design controls, and quality systems for CE certification. David's group often audits existing quality systems to bring them into FDA and ISO 13485-compliance. With his emphasis on engineering, I like to use David's group technology-intense projects.

Protocol development and study design

Meet Patsy Trisler

Patsy is one of those multi-talented people that can do anything regulatory or clinical. She is listed here under protocol development and study design, but could be listed under IDE approvals or regulatory submissions. To give you an idea of her breadth, here is a list of technologies for which she has provided strategic guidance: allograft tissue applications, blood processing technology, dental products, drug delivery devices, dura substitutes, interventional cardiovascular therapies, orthopedics (including bone replacements/substitutes, bone

growth stimulators, growth factors & spinal technologies), pain therapy technologies, plastic & reconstructive cosmetic & rehabilitative products, soft-tissue reinforcement implants, software (medical), weight-loss products, and wound care therapies.

Meet Cheryl Hayden

Dr. Hayden is educated as a microbiologist, has research experience in cancer epidemiology and biostatistics, and has hands-on experience in clinical research. She has prepared over thirty clinical evaluation reports on the performance of different kinds of medical devices. Although she has a broad range of expertise, her specialty is diagnostic devices and biomarkers.

Meet Barry Sands

Barry is a biomedical engineer with a chemical engineering concentration. He has seven years experience as a Biomedical Engineer and Sr. Scientific Reviewer at FDA/CDRH/ODE and FDA's Boston District. This government experience was followed with seventeen (17) years in midlevel and executive regulatory/clinical/quality affairs management positions in small start-up and large multinational medical device companies. His firm provides support in the areas of regulatory submissions (510k, IDE, PMA, HUD/HDE, Design Dossiers), Clinical Study Design/Management, Risk Management, Quality System Design/Audits (FDA QSR and ISO 13485) and FDA Negotiation and Communication (QSR Audits, 483s, Warning Letters, Bioresearch Monitoring, Medical Device Reports, Recalls).

Sample size calculations and statistical development plan

Meet Michelle Secic—biostastician

Michelle Secic, MS has worked on hundreds of protocols and the full range of devices, biologics, and drugs in her years as Manager of Statistical Analysis at Cleveland Clinic. She knows a protocol's sample size must be based on defensible estimates. She will work with you to design a study that gets you the indications you need with the least number of subjects. "Work with the words" she agrees. Michelle knows from experience that measuring the time to heal a wound versus the number wounds healed at a given time will lead to very different sample sizes. She will work with the performance estimates you provide to give you a table of possible sample sizes.

Meet Dr. Robert Thiel—Bayesian and IVD specialist

Dr. Robert P. Thiel has degrees in physics and psychometrics. He is an expert in the analysis of IVD data for the Medical Device Industry with more than seventy-five 510K and five PMA approvals. He has published papers in the areas of free PSA, breast cancer, ovarian cancer, liver disease and multivariate analyses. His current interests lie in the area of bootstrap and permutation test methodology and the application of these methods to small sample trials and Bayesian analysis as applied to diagnostic clinical trials.
Project management

Meet Lynette Chiapperino—Monitor and Clinical Project Manager

The Clinical Trial Project Manager is the person who plans the study and provides forward motion to the clinical trial. Lynette Chiapperino, AAS in medical technology and BS in management, is a born clinical trial project manager. She can estimate time, cost, and human resources needed for a trial. She understands both the sponsor's and investigator's responsibilities and works both sides of the aisle when monitoring a study so that everyone's records are in order.

South of the border

Meet Patricia Hamilton—Regulatory, Monitor, and Project Manager

Patricia Hamilton is a Registered Nurse with a Master's in International Business. She specializes in both domestic and international clinical trial management with a focus on South America. She has DSMB and FDA experience. She has designed, implemented and completed pediatric device trials early and on budget. Her background as an emergency department nurse director and a clinical director for Fortune 100 companies give her the

ability to relate to physicians and nurses, understand hospital policies, and accomplish sponsor study goals.

Case report forms and other study documents

Meet Dr. Nancy Stark

Dr. Stark has some pretty good skills with MS Visio and often works with the protocol designer, statistician, and data manager, to layout the case report forms. The goal is to make the forms easy for the form-filler and easy for the data-enterer, while following the protocol exactly. Three-part paper forms are still the best way to collect data for small studies or small companies.

Study implementation

Meet Sue Lesly

Sue Lesly is educated with a BS in English and psychology, which explains her diverse clinical research experience. She has been involved in all aspects of clinical trial performance including: monitoring, site recruitment, site management, CRA & CRO management, protocol development, CRF & source document design, development of study specific procedures & internal clinical SOPs, and preparing reports for FDA & regulatory submissions.

Meet Kathleen and Lynette-monitors

Yes, these are the same Kathleen Johnson and Lynette Chiapperino you met above. Multi-talented, Kathleen, Lynette, and Sue (above) are CDG's go-to people for day-to-day monitoring.

Data Safety Monitoring Boards and Clinical Events Committees

Meet Steven Schurr, Esquire

More complex products or those with new technologies often require a Data Safety Monitoring Board or Clinical Events Committee to adjudicate adverse events; i.e., make the final call as to whether an adverse event is device related or not. CDG's Steve Schurr, Esquire has the clinical, legal, and DSMB experience to manage this external board of independent experts.

Data management

Meet Wessam Sonbol

Wessam Sonbol has a BS in computer science and business management, and he uses these skills effectively to design databases to receive clinical data (Wessam is proficient in Access, Excel, Clindex and other applications), validate the database, import data, and verify the data. He is comfortable with Part 11 controls and able to advise you as to how and when controls should be implemented. Wessam has over 11 years of experience in Clinical Data Management.

Reimbursement, comparative effectiveness, cost effectiveness

Meet Vincent Jaeger, MD

As you know, FDA clearance is the first hurdle, getting Medicare reimbursement or third-party coverage for your technology is the second hurdle. In addition to his practice as a thoracic and cardiovascular surgeon, Dr. Vincent Jaeger brings to the table experience as the National Medical Director for Coverage and Reimbursement at AETNA and then at Health Net. This expertise gives him the background necessary to assist you in obtainig

third-party reimbursement for your technology or in designing reimbursement, comparative effectiveness, or cost effectiveness clinical studies.

We can help you; hire us as your CRO

Clinical Device Group has the capabilities to perform all of these tasks for you—we are a full-service CRO. But if you prefer, hire us to perform specific tasks or act as an advisor to your staff.

Best Regards,

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