Michael Nordsiek, BS
Chief Executive Office

Over 30 years experience in Technical Operations, Supply Chain Management, Regulatory Affairs, Project Management, Quality and Product Development.

Dror Rom, PhD
Chairman and President

Over 25 years experience in statistics applicable to design and analysis of clinical trials including numerical computations, bioequivalence, multiple comparisons, and adaptive designs. Numerous publications including the co-authoring of a SAS book on multiple comparisons.

Sharon Levy, MD, FCCP
Chief Medical Officer

Over 20 years experience; board certified in internal medicine, pulmonary and critical care medicine. Extensive experience in all aspects of Phase I through IV clinical trials, as well as in medical affairs and pharmacovigilance support.

James Kulp, BS
Vice President, Clinical Research

Over 20 years experience in strategic planning and execution of non-clinical and clinical studies (Phase I through IV). Successful management of multiple clinical programs utilizing Clinical Research Organizations and Internal resources. Author of numerous clinical study protocols and other study-related documents.

Robert Babilon, MS, MBA
Vice President, Regulatory Affairs and Quality Assurance

Over 25 years experience in development and approval of pharmaceuticals and medical devices. Organized and led numerous meetings with FDA and Health Canada. Author of numerous IND and NDA documents.

Other Services include:

Biostatistics

- Protocol development
- Sample size determination
- Statistical Analysis Plan
- Randomization
- Statistical Analysis
- Data Safety Committees
- Report ready analysis tables

Data Management

- Case Report Form Design
- Database design and validation
- Data entry
- Programmed edit checks
- Adverse event coding
- Medication coding

Clinical Operations

- Clinical trial tracking and monitoring
- SOP writing
- Vendor contract negotiations
- Resource Planning

Regulatory Operations

- Coordination of NDA Submissions
- Preparation of ISS/ISE and other clinical sections
- Compilation of NDA sections
- Quality assurance

Prosoft Clinical and Adaptive Designs

Prosoft's statisticians have been on the forefront of research and implementation of adaptive designs in various areas of clinical research. Partnering with DANA Pharmaceuticals and Stanford University, Prosoft received an NIH grant for the commercialization of an adaptive design software for cancer research. While not every study is suitable for adaptive design, consultation with Prosoft can help you better assess the multiple factors affecting the conduct of your study, leading to a better chance of a successful conclusion of your trial.

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PROSOFT Clinical

The Power of Experience

PROSOFT CLINICAL

Established in 1995, Prosoft Clinical is a Pharmaceutical product design and development organization with CRO capabilities:

Consultative Services

Vast therapeutic expertise with drugs and devices

Clinical Trial Management

Set up studies with regulatory documentation, IRBs, contract negotiation with clinical centers, medical monitoring

eTechnologies

Cost efficient solutions to help manage clincial studies

CONSULTATIVE SERVICES

Consultation with Prosoft Clinical experts can improve the strategic design and execution of clinical programs for pharmaceutical products and medical devices. Our broad experience allows us to work closely with sponsors to proactively identify and address potential roadblocks to development. The Prosoft Clinical team has extensive experience interacting and negotiating with Regulatory Authorities, including the FDA and Health Canada. Prosoft team members have participated in IND/IDE, End-of-Phase II, pre-NDA/PMA, labeling and FDA Advisory Committee meetings leading to the approval of numerous drug and device products.

CLINICAL TRIAL MANAGEMENT

The Prosoft Clinical team has hands-on experience in all aspects of product development from preclinical studies through NDA/PMA submissions. Our team is an extension of your team. Our highly experienced clinical research professionals will seamlessly drive the process from concept through reporting of study results. From managing small Phase I studies through large Phase III studies, you can count on Prosoft Clinical to deliver high-quality data in a cost-efficient manner. We take pride in your success!

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eTECHNOLOGIES

Our state-of-the-art web-based platforms allow us to launch and manage studies efficiently with a quick start-up and database lock, providing you results as soon as last patient completes last visit. Our systems include:

eDC

- eCRF data management system
- Entry through web browser, available 24/7 worldwide
- Real time web reports, AE/Med coding
- Real time edit checks
- Query management system
- CFR 21 Part 11 Compliance

eNroll: IWRS/IVRS

- Rapid enrollment and randomization of subjects by phone or internet
- User friendly, logical call flow
- Complete IP management with automated triggers and email/fax requests and alerts
- Advanced security features

eDSMB

- Set up your Safety Monitoring Board
- Write charters
- Manage meetings
- Produce data summaries for review