

DEVELOTRON LLC

Clinical Research and Development

Develotron, LLC provides clinical development consulting and implementation services to the biopharmaceutical industry. Professional services range from strategic planning to trial implementation.

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Page 1

- Develotron and Biotech
- Key to Effectiveness
- Develotron Approach
- Engage Develotron

Page 2

- Service Offerings
 - Strategic Services
 - Tactical Services
- Consultants

Page 3

- Critical Questions
- Contact Develotron

Develotron and Biotech

Develotron understands the unique needs of our early-stage biopharm clientele. The foundation for future success depends on a successful initial entry into clinical trials. However, acute resource constraints require a creative approach to establishing and implementing a suitable clinical development plan.

Simplicity Delivers Efficiency and Effectiveness

In the struggle between high quality, low cost, and speed, Develotron has found that Simplicity can be the key element that allows our clients to optimize all three parameters simultaneously. Develotron delivers clinical R&D services in the most efficient and effective manner possible, with solutions tailor-made for the emerging biopharm sector.

Approach

Develotron focuses on maximizing value for our clients' projects through careful resource and financial management. In most cases, for example, we can trim away excess costs from a proposed CRO quotation, or identify and eliminate unnecessary and costly operational elements from a draft clinical protocol. Develotron can deliver a significant return on costs even before a project starts.

Engage Develotron

We offer our consulting and implementation services in a flexible manner to suit our clients' needs. From a one-time review of a DSMB operational plan to serving as Acting Clinical Operations Director, all projects will be completed to the highest possible standards and according to the negotiated budget.

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Service Offerings

Develotron provides clinical development support to emerging biotechnology and pharmaceutical companies, from strategic planning through trial implementation.

Strategic Services

- Clinical development planning
- Budget forecasting and analysis
- Due diligence evaluations
- Clinical operations administration:
 - System analysis and development
- Clinical SOP development
- CRO selection:
 - RFP preparation
 - Budget negotiation
- Protocol development

Tactical Services

- Clinical trial implementation:
 - Protocol, budget/timeline, site, vendor, and line management
- CRF development
- Data management interface
- Central laboratory selection:
 - Technical specs, budgets and contracts
- Clinical site audits
- Clinical monitoring
- Data review and medical writing

Consultants

Stephen Fogelson, M.S. is the Founder and President of Develotron, LLC. Mr. Fogelson's clinical research career spans 20 years, the last 15 years in the biotech sector. He has held both tactical and strategic industry positions and has successfully fulfilled numerous consulting contracts. Throughout his career, his approach has been to identify core elements of project requirements in order to distinguish essential from non-essential functions. This has allowed him to develop a streamlined approach to program design and implementation which is of critical importance in the emerging biotech arena. Mr. Fogelson's expertise targets the development of programs requiring creative solutions due to technical complexity or resource constraints.

Therapeutic Expertise

- Oncology
- Infectious disease
- Allergy and immunology
- Respiratory disease
- Dermatology
- Arthritis
- Wound healing
- Digestive disorders
- Cognitive dysfunction
- Diagnostic indications

Develotron has an established **network** of highly experienced consultants in key areas of pharmaceutical development, including:

- Pre-clinical R&D
- Regulatory Affairs
- CMC / Manufacturing
- Biostatistics
- Data Management
- Clinical Trial Management and Monitoring

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Develotron supports early-stage planning

While our clients may be one or two years away from entering clinical trials, they will rely on our clinical development work to establish financial, manufacturing, regulatory, and non-clinical R&D decisions. We can help provide answers to the important drug development questions at any stage of the product's life-cycle.

Develotron can answer these questions

- What is the target indication and patient population for our product?
- What is the expected clinical research time and cost for development in this indication?
- Are there alternative development routes that will allow us to streamline the process?
- How fast can we reach our corporate milestones?
- What will my Phase I study look like, how long will it take, and how much will it cost?
- How many subjects will I need to enroll?
- How much drug will I need for my early phase trials?
- What type of pre-clinical toxicity data will I need to enter clinical trials?
- How do I make sure my protocol includes all the essential elements?
- When do I need to write my first clinical protocol?
- How do I meet and contract with key opinion leaders?
- What type of SOPs will I need to enter clinical trials, even if key functions are outsourced?
- What level of internal staffing is needed to manage early-phase studies?
- How do I select a suitable CRO?
- How do I make sure my CRO is giving me the best price and all the services I will require?

Contact Develotron

To engage Develotron services or to join the Develotron network of consultants, please contact Stephen Fogelson: 508-404-6379; SFogelson@DevelotronLLC.com