

Danik Innovations LLC offers a unique blend of clinical strategy development and implementation expertise for our clients in the pharmaceutical industry.

We assist our clients in designing, implementing and reporting of global clinical development programs in various therapy areas including: vaccines, immunology, infectious diseases, cardiovascular, and respiratory. We offer clients the benefit of our extensive expertise in clinical trial planning, data review, interpretation, medical writing, submissions, and review of clinical documents from Phase 2 through Phase 4 of clinical development.

## CLINICAL DEVELOPMENT CONSULTANTS



### **BUSINESS DEVELOPMENT & CLINICAL STRATEGY**

- Generate Executable Clinical Development Plans
- Review and Interpretation of Clinical Data
- Critical Review of Clinical Plans for Fast-Track and Breakthrough Designation Status
- Support Comprehensive Due Diligence Activities



### **MEDICAL WRITING**

Write & Review Clinical Documents from Pre-Study to NDA, BLA & MAA Submissions in Multiple Therapy Areas

- Protocols & Amendments
- Study Reference Manuals
- Informed Consents & Assents
- Investigator Meeting Materials
- Clinical Study Reports
- Safety Updates & Narratives
- Clinical Section of Pre-IND and IND Documents
- Overviews & Summaries of Efficacy & Safety
- Manuscripts for Publications

## **DELIVERING INNOVATIVE BUSINESS SOLUTIONS**