cros nt | Where Data Expertise Meets Clinical Excellence

MEDICAL DEVICE FACT SHEET

Pre- and Post-Market Study Services

CROS NT aids companies in the start-up phase helping prepare their data with due diligence in mind for presentation to potential funders and developers using a centralized data approach.

We support late stage device companies through expert statistical analysis and consultancy for regulatory submission as well as support during the regulatory process.

CROS NT HAS WORKED WITH NUMEROUS COMPANIES HELPING THEM PLAN THEIR CLINICAL STUDIES, STATISTICAL ANALYSES AND DEVELOPMENT PLANS FOR A SUCCESSFUL REGULATORY SUBMISSION

SERVICES
BIOSTATISTICS
STAT PROGRAMMING
DATA MANAGEMENT
MEDICAL WRITING
REGULATORY

TECHNOLOGY
EDC
ECOA
IWRS
CLINICAL DATA VISUALIZATION

WE OFFER A FULL SPECTRUM OF STATISTICAL AND DATA MANAGEMENT SERVICES FOR NOVEL, CLASS III DEVICES AND DE NOVO CLASS II DEVICES

CONSULTANCY
GLOBAL CLINICAL DATA STRATEGY
REGULATORY SUBMISSIONS
TRIAL DESIGN & METHODOLOGY
ADAPTIVE TRIAL DESIGN
RISK-BASED MONITORING

Medical Device Experience

- 250+ medical device, diagnostics and imaging studies completed in the past 5 years
- 15% of studies resulted in regulatory submissions including IDE, 510(k) and PMA
- Biostatisticians with 20-35 years of experience
- Top therapeutic areas: orthopedics, cardiovascular, respiratory, diabetes, oncology-related devices
- FDA and EMA regulatory advice

www.crosnt.com