



**cros nt** |

Where Data Expertise  
Meets Clinical Excellence

# MEDICAL DEVICE FACT SHEET

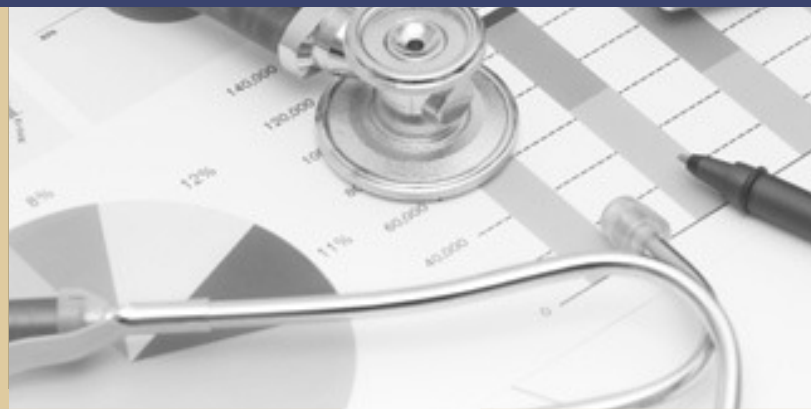
## Pre- and Post-Market Study Services

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  
ECO  
IWR  
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