FDA & REGULATORY EXPERIENCE

Let Your Data Grow®

Stat One has extensive experience supporting clients in interactions with the FDA. Our experience includes:

- Attending panel meetings
- Addressing questions related to study design and sample size
- Responding to deficiency letters
- Providing statistical analysis and programming information

SUBMISSIONS

Let Your Data Grow®

- Stat One has supported for the following types of products:
  - PMA and 510(k) clinical studies
  - Biologics
  - Pharmaceutical agents

- Stat One has contributed to studies that included:
  - Sample size re-estimation and/or group sequential analyses
  - De novo medical devices
  - First of type products

- Stat One has also supported studies and submissions in Europe

- Stat One has extensive experience with post marketing and registry studies