

# DSI's Proven Nomenclature Experience Provides Excellence with Regulatory Agency Submissions

## Name Submission Strategies

### General Guidelines

- Submit data to regulatory agencies as soon as possible after nomenclature safety research is completed
- Submit custom-tailored DSI FDA and/or EMEA reports rather than entire study
- We recommend that a new study be conducted on data more than one year old
- File trademark application with local trademark authorities as soon as possible

### FDA

- Submit a DSI FDA Report as early as Phase II of an IND
- Submit 1 or 2 name candidates (designate primary and alternate)
- Initial review upon submission. Final review 90 days prior to NDA approval

### EMEA

- Submit a DSI EMEA Report as early as 12 months, but no later than 4 months prior to the submission of the MAA (Marketing Authorization Application)
- Submit up to 3 name candidates

“Drug Safety Institute strongly suggests that our clients submit FDA/EMEA reports with favorable nomenclature results to regulatory agencies. Submitting favorable nomenclature research with your regulatory request for proprietary name approval will help minimize Agency concerns or objections and lead to higher approval rates.” - J. Phillips



*Jerry Phillips, R.Ph.,  
President, Drug Safety Institute, Inc.*

Under the leadership of Jerry Phillips, R.Ph., who served 16 years with the Food and Drug Administration (FDA), Drug Safety Institute (DSI) continues to build a great track record with naming research and regulatory submissions.

**Brand Institute and Drug Safety Institute are pleased to have worked on the following recent brandname development initiatives:**

**ENJUVIA**



**EQUETRO**



**EVOCLIN**



**FEMTRACE**



**LUNESTA**



**TRUVADA**



**TYSABRI**



**VENTAVIS**

