

# New and Evolving Regulatory, Legal, and Quality Issues to Examine DIA Statistics Forum

21st Century  
Cures Act analysis  
and implementation

## PDUFA VI Commitments related to statistics:

- Patient-focused methods to inform drug development and regulatory decisions
- Advancing model-informed drug development through facilitating the development and application of statistical models
- Increasing capacity to review complex innovative drugs
- Advancing postmarket drug safety through expansion of the Sentinel system

ICH Guidelines  
(E9, E17, and E14)  
updates and impact

Alternative data sources for  
evidence generation for early  
studies, clinical trials, and  
postmarketing studies

New review processes'  
impact on trial design  
and analysis

**#Stats17**  
**DIAGlobal.org/Stats17**

