REGULATORY AFFAIRS
ANIMAL HEALTH



## Data Management in Animal Health Studies





What is data management?

Data management is the sum of the processes you wrap around your data to ensure the integrity of your data.





# "HOPE IS NOT A STRATEGY."

**USAF Special Ops pilot** 



Issues around data integrity continue to be one of the top findings by CVM.

- 2013 Data Quality Webinar
- 2015 Implementation of QASR
- 2016 GFI Data Integrity and Compliance with Current Good Manufacturing Practice



Having well integrated data management is vital in addressing these issues.

 Bonus - it also facilitates study design, conduct and reporting.



Today's presentations provide a strong combination of high level data management concepts and detailed information.

- Elements of Data Management
- Raw Data and Data Management
- Contents of a Data Management Plan
- Data Management Considerations in EDC Study Setup







2013 Data Quality Webinar

https://wayback.archive-

it.org/7993/20161022070921/http://www.fda.gov/

AnimalVeterinary/NewsEvents/WorkshopsConferen

cesMeetings/ucm348902.htm

170+ slides

35 page transcript

37 pages of Q&A





