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# DFUG Vendor Audit 2015

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# Audit Details

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Date: Monday the 5<sup>th</sup> of October and  
Tuesday the 6<sup>th</sup> of October 2015

Auditors: **Michael Holdsworth**

Senior Data Analyst, National Institute of Allergy and Infectious  
Diseases, Rockville MA, USA

**Manisha Thakur**

Validation Specialist, Population Health Research Institute,  
Hamilton, Canada

# Audit Scope

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- DF/Net Research, Inc. is now a combined organization that is both a software vendor and a service provider.
- As a service provider, DF/Net provides a range of services, such as hosting services, CRO, data management, and training.
- However, it is important to define that this is a software vendor audit.
- We are only concentrating on DF/Net's infrastructure/ processes/documentation that relate to the maintenance, development, and distribution of the DataFax software.

# Audit Activities

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- Overall quality management
- Personnel qualification and training
- Software development methodology
- Supplier and sub-contractor management
- Project management
- Quality control processes
- Quality assurance processes
- Merger management
- Security
- Disaster preparedness
- Physical server and file rooms
- Financial stability
- Outcomes from other audits and regulatory inspections
- Follow-up from previous DFUG vendor audits

# Audit Characteristics

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- Representative of the entire DataFax user group
- Offers value to the entire group
- In this spirit, we pre-distributed the Audit Plan
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