

---

# Development of Oncology Databases at Inovio

Sandra Oyola, CCRP

Inovio Pharmaceuticals, Inc.

Plymouth Meeting, PA



# Development of Oncology Databases at Inovio

---

- DFUG 2012:
  - Inovio's experiences with setting up and learning DataFax
  - Paper-based studies
  - Study start-up and closure

# Development of Oncology Databases at Inovio

---

- DFUG 2014:
  - Starting up our ninth DataFax study
  - No more paper
    - Moving to EDC
  - Several new oncology studies

# Development of Oncology Databases at Inovio

---

- Our challenge: where to start?
  - New indications
  - New kinds of data to be collected
  - More complex edit checks
  - Training for sites and monitors

# Development of Oncology Databases at Inovio

---

- New indications
  - Oncology is unlike our other studies (healthy volunteer, infectious disease, women's health)
    - Breast, lung, pancreatic, head and neck, cervical
    - Each of these types of cancer is different from the other
  - Resources required for planning and execution

# Development of Oncology Databases at Inovio

---

- Planning
  - Oncologist feedback
  - Study Investigators
    - Assist in development of CRFs
    - Review publications
  - Public websites/resources
    - EORTC – RECIST
    - RTOG – Imaging-specific CRFs
    - EMBRACE and OUTBACK

# Development of Oncology Databases at Inovio

---

- New kinds of data to be collected
  - Each oncology indication has unique data
    - Imaging – unique for each study
      - PET/CT, X-rays, MRI
        - RECIST, SUV
    - Pathology/tissue sampling
    - Specific testing for eligibility
    - Chemotherapy and radiation regimens

# Development of Oncology Databases at Inovio

---

- CRF and database design – collect the data we need
  - Imaging
    - PET/CT – SUV
    - MRI or CT - RECIST
  - Pathology/tissue
    - ISH, IHC, other tests
  - Chemotherapy and radiation regimens
    - Cycles, doses, frequency



# Development of Oncology Databases at Inovio

---

- More complex edit checks
  - More than date ranges and blank responses
    - Timing of regimens/surgery in relation to enrollment or dosing
    - Changing data after PI signature
    - Checks across CRFs
    - Autopopulate CRFs
    - Look-up tables (LUT)

# Development of Oncology Databases at Inovio

---

- How did we handle programming?
  - Once again, we used our trusted friends RPXP and DF/Net
    - RPXP: CRF design and help with design, visit maps
    - RPXP brought in BB to program the edit checks and LUT
    - DF/Net took over later study development

# Development of Oncology Databases at Inovio

---

- Training
  - Multiple sites, multiple studies
  - Sites were required to download DF to their workstations
  - DataFax was new to all of our sites and our new clinical personnel

# Development of Oncology Databases at Inovio

---

- Approach to training
  - GoToMeeting set up
    - DF/Net performed the “generic” training
      - Training was documented
    - Inovio performed the study-specific training
  - CRF completion guidelines
  - Help desk was set up
    - Downloads, passwords, etc.

# Development of Oncology Databases at Inovio

---

- Additionally:
  - UAT was performed by at least two people
  - SOPs and work instructions
  - Refresher training for sites and staff
  - Standardization
    - Edit checks, CRFs

# Development of Oncology Databases at Inovio

---

- In summary:
  - As oncology is so unique, a unique approach was required
    - Oncologists' feedback was very valuable
    - Other studies with public websites
  - Good learning experience
    - We can reduce development time for future studies
    - Standardize CRFs and edit checks

# Development of Oncology Databases at Inovio

---

- Special thanks to:
  - Our friends at DF/Net (Darryl, Lisa, Jae)
  - RPXP and BB (Valerie and Bonnie)
  - Inovio Pharmaceuticals Clinical Development and IT
  - Everyone at CDSI

# Development of Oncology Databases at Inovio

---

