"Workshop Charge"

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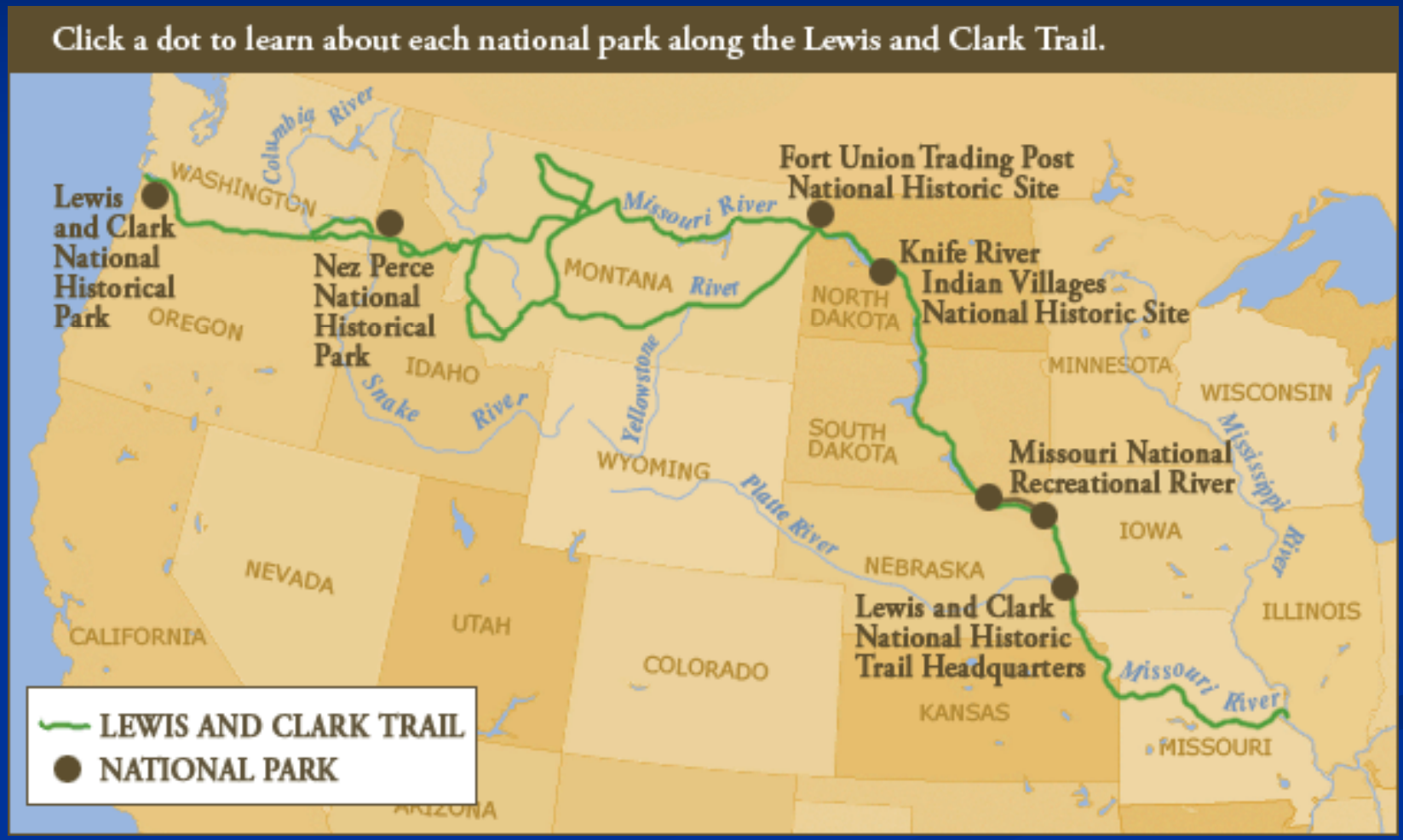
Imaging Workshop : April 13, 2010

Blazing a Trail Together…



Our Imaging "Expedition"

Why?

- Why are we embarking on this "Expedition"?
  - Guidances, Standardization, Predictability in Product Development

How?

- Why Guidances?
  - Provide recommendations, increases transparency, decreases risk?
- Did others accompany Lewis & Clark?
  - Yes…How many survived the trip?

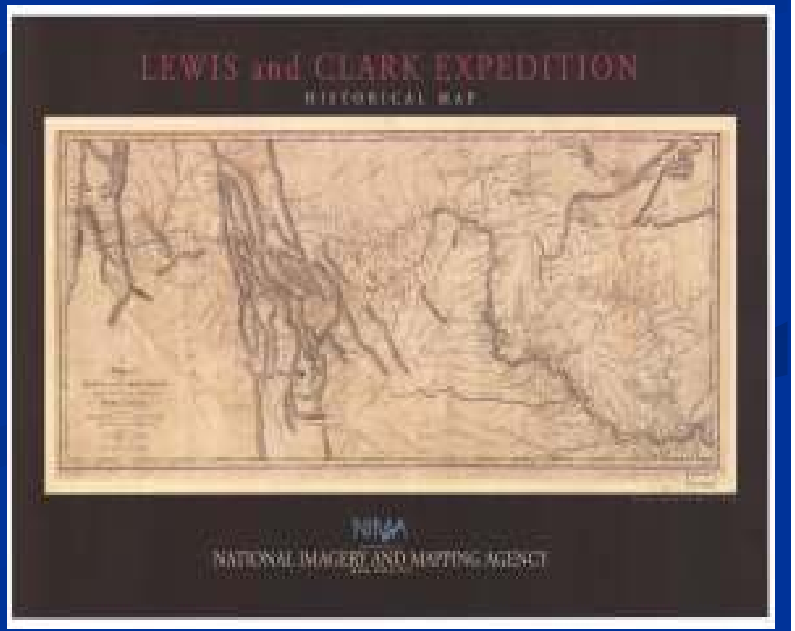
Now?

- Series of questions…to be answered
- Can I follow previous routes?

http://www.lewisandclark.com

The Guidance "Expedition"

- Background:
  - PDUFA IV, signed in 2007, called for the development of a guidance to address "*Imaging Standards for Use as an End Point in Clinical Trials*"
- How:
  - Together, starting today!!
  - Identified some hurdles (Questions)
  - Consolidate input
- Next:
  - Inform Guidance
  - Improve clinical trials
  - Improve product development
  - Help patients



STANDARDS FOR IMAGING ENDPOINTS AND MANUFACTURING OF PET RADIOPHARMACEUTICAL PRODUCTS IN CLINICAL TRIALS

APRIL 13–14, 2010 · NATCHER CONFERENCE CENTER

RSNA SNM FDA

Breakout Session 1: Image Acquisition

(Room E2)

Co-chairs

Kyle Myers, Ph.D., Orhan Suleiman, M.S., Ph.D.,F.A.A.P.M.,
Michael Graham, Ph.D., M.D. Greg Sorensen, M.D.

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Breakout Session 2: Image Interpretation

(Main Auditorium)

Co-chairs

Nicholas Petrick, Ph.D., Barbara Stinson, D.O.,

Peter Conti, M.D., Ph.D., Lawrence Schwartz, M.D.

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Breakout Session 3: Management of Imaging Data

(Balcony C)

Co-chairs

Aldo Badano, Ph.D. , Alex Gorovets, M.D.

John Hoffman, M.D., Brad Erickson, M.D., Ph.D.

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Breakout Session 1: Image Acquisition

1) Are there specific prescriptive tests that should be conducted to standardize the image acquisition and imaging equipment performance?

   A. Are physical tests with phantoms, or clinical protocol specifics such as subject positioning and timing of images necessary in order to standardize across multiple sites?

2) How do you select the appropriate imaging modality?

A. How do the imaging goals of the trial drive the choice of specific modality?

(Detection of an abnormality? Measurement of some anatomical and functional property? Assessment of response to therapy in terms of some measured value – diameter, volume, density or some other measure of morphology, some measure of function such as perfusion?)

3) How can we ensure that clinical trials perform all of the necessary testing to ensure consistency and standardization of image acquisition?

A. Focus on a certification/accreditation/attestation/audit process, with these groups ensuring adherence to protocol?
B. Focus on actual physical tests (which phantom and how it relates to clinical task, equipment quality control)
C. Standardization of the entire clinical protocol, subject positioning, geometry, timing of tests
D. All of these, some of these?


Mount Image
Chasm
Early Pioneer/s

Have:

- Questions
- Experience
- Template

Need:

- Answers
- Leadership
- Deadlines

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Breakout Session 2: Image Interpretation

FDA Chairs: Nicholas Petrick, Ph.D. and Barbara Stinson, D.O.
Co-chairs: Peter Conti, M.D., Ph.D. and Lawrence Schwartz, M.D.

1. Please comment on the challenges posed by large-scale, multi-center national clinical trials, how on-site/investigator parameters are standardized, and how results are managed. Please address potential issues of discordance between site and central reads and the management of these issues. In addition, please provide examples of management of these trials including image interpretation aspects by various organizations.

2. Please discuss and prioritize approaches to reduce image interpretation variability in clinical trials (e.g., the need for standardization of software, software tool standards and onsite electronic data capture) and note which of these approaches are the most practical to implement. Discuss the appropriate management of clinical data in trials that use imaging results as an endpoint.

3. What is the role of the report (and image annotations) performed by the radiologist rendering the official reading? How does this relate to the on-site reads of the study team? If there are discrepancies, how should this be addressed? Is it possible to develop a standard CRF that is applicable to most clinical trials that use imaging or to develop a CRF that may be used by both on-site and central readers?

Shoot for the bull's-eye!

CHARGE!

Answer all questions!

↓

If appropriate, add to the questions…answer them!

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Session leaders:

- Consolidate take-home messages
- Develop summary
- Present at 8:30 tomorrow

↓

***Outcomes will, as appropriate, incorporated into draft Guidance**

* ***Can add to outcomes after***

"The Best Way to Have A Good Idea…
Is to Have Lots of Them"

Linus Pauling, 2X Nobel Laureate