

Project Data Sphere

Images and Algorithms: Program Overview

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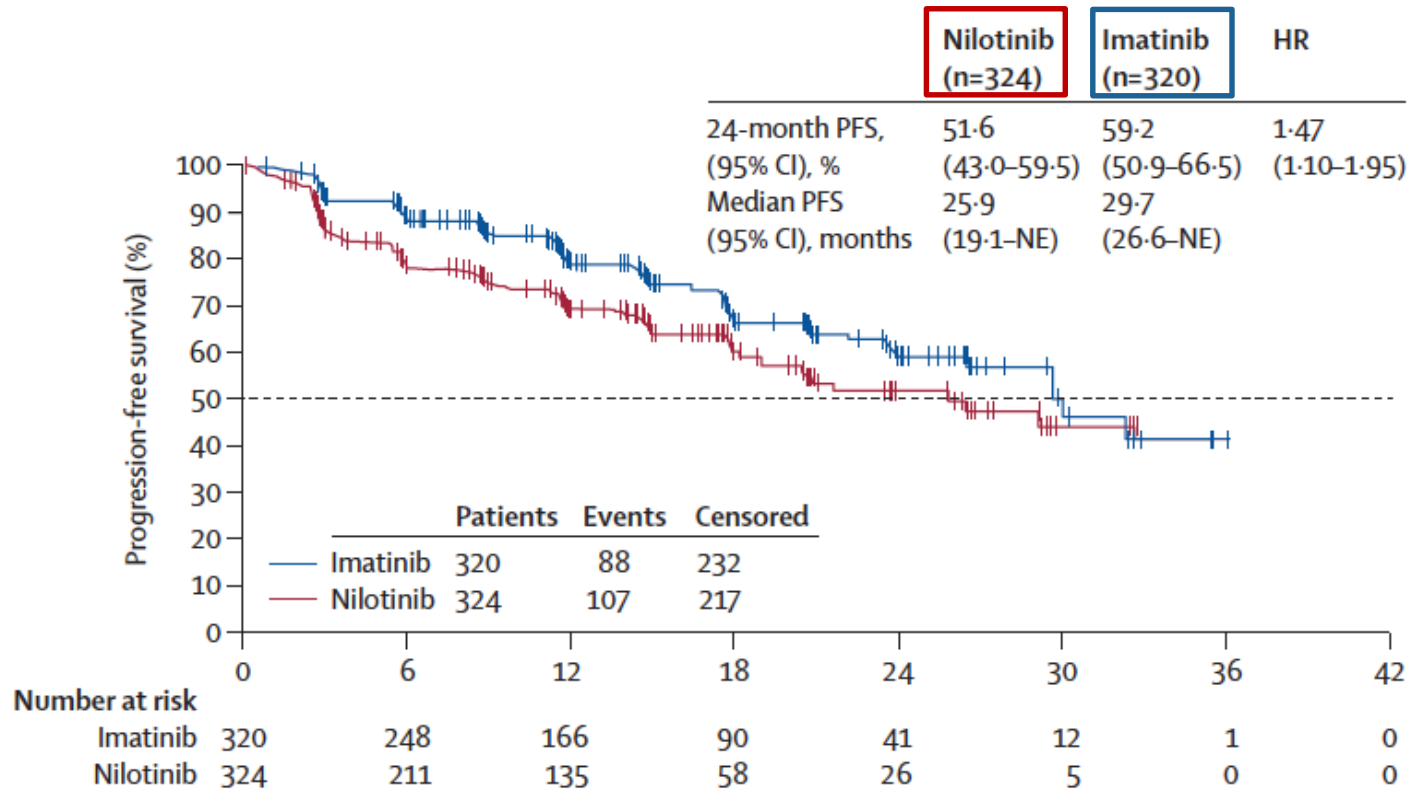
DISCLOSURES FOR GEORGE D. DEMETRI, MD

- **Scientific consultant:** Bayer, Pfizer, Novartis, Lilly, Roche, Epizyme, LOXO, AbbVie, EMD-Serono, GlaxoSmithKline, Janssen, PharmaMar, ZioPharm, Daiichi-Sankyo, Polaris, Sanofi, AdaptImmune, Ignyta, Mirati, ICON plc, WIRB-Copernicus Group, MJ Hennessey/OncLive, MEDSCAPE
- **Consultant/SAB member with minor equity holding:**
G1 Therapeutics, Caris Life Sciences, Champions Biotechnology, Bessor Pharmaceuticals, Erasca Pharmaceuticals
- **Independent Member of Board of Directors and Scientific Advisory Board Consultant with minor equity holding:**
Blueprint Medicines and Translate Bio

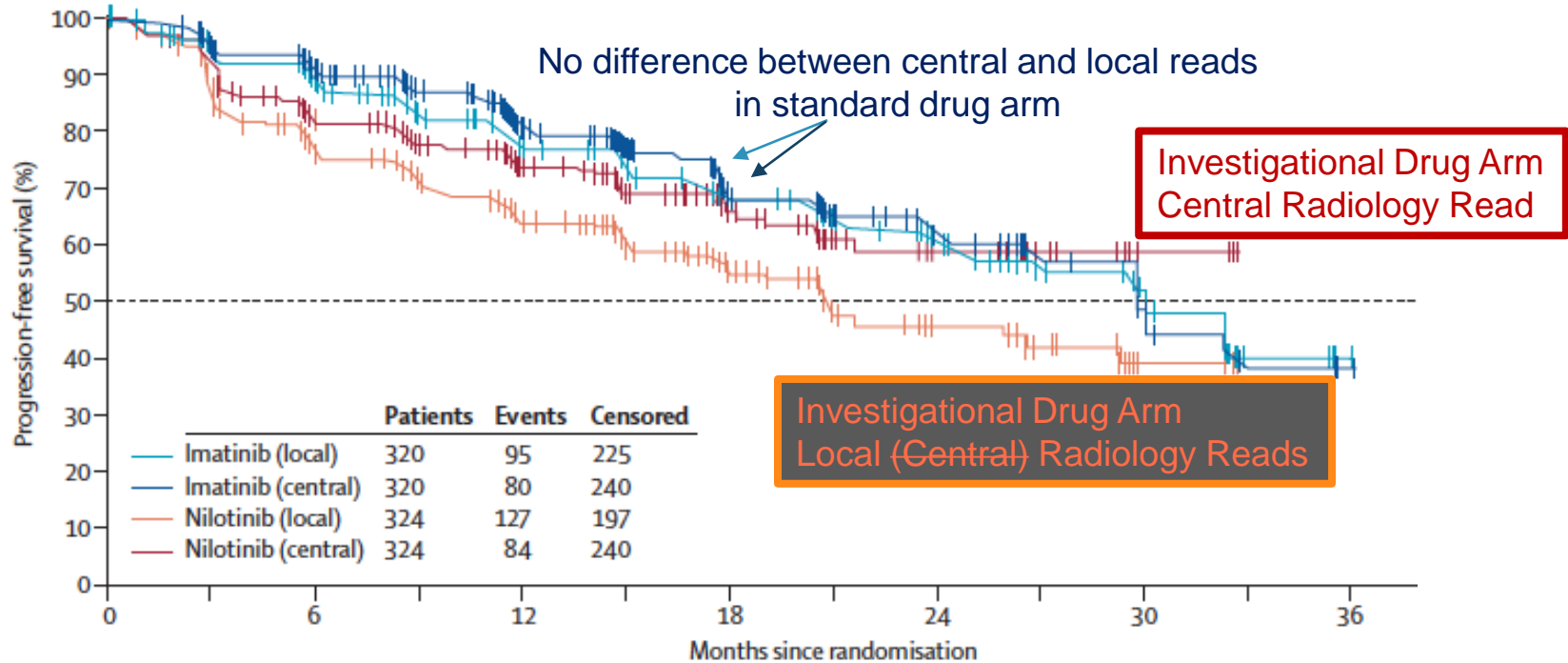
Images and Algorithms Program: Background

- Cancer imaging represents a universally-used clinical tool to assess patients endpoint
- Imaging is frequently used as a metric to assess the impact of anticancer therapy, for clinical care and/or for research trials
- The interpretation of cancer imaging studies can be more subjective than might commonly be known by the public

Imaging of Malignant Tumors (GIST) in a Phase 3 Clinical Trial



Imaging of Malignant Tumors (GIST) in a Phase 3 ***OPEN LABEL*** Clinical Trial



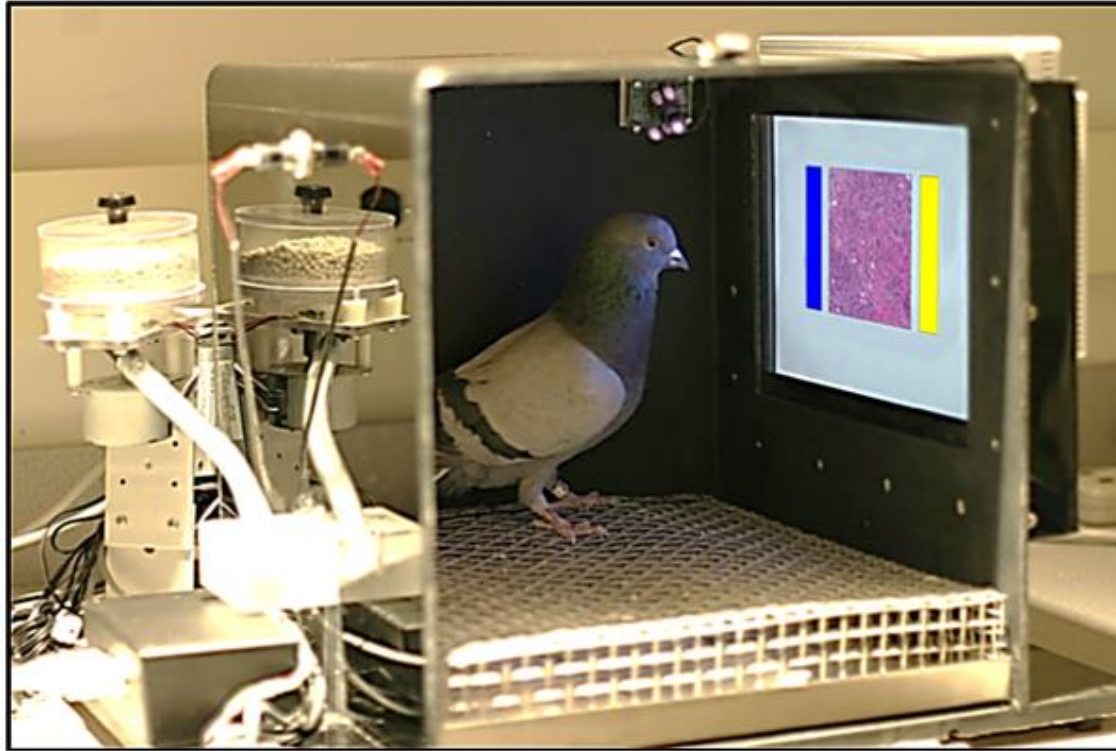
Challenges with the Current State

- Central radiology reviews are slow, cumbersome and very expensive
- Clinical decisions often require rapid turn-around and extremely high reliability
- Assessment systems ignore much available data from imaging

Might Artificial Intelligence/Machine Learning Improve the Consistency of Interpretation for Cancer Imaging?

- Inters-observer differences exist for many reasons
 - Choice of target lesions to measure
 - Choice of dimension to measure for complex 3D tumor mass
- Pattern recognition can be done in many ways to complement human judgement

Pigeons can be trained to recognize cancer vs. not-cancer in breast tissue



Levenson RM, Krupinski EA, Navarro VM, Wasserman EA (2015) Pigeons (*Columba livia*) as Trainable Observers of Pathology and Radiology Breast Cancer Images. PLoS ONE 10(11): e0141357. doi:10.1371/journal.pone.0141357
<http://journals.plos.org/plosone/article?id=info:doi/10.1371/journal.pone.0141357>

Goals for PDS Images and Algorithms Program

- Bring together a community aligned to develop, test and validate novel tools for interpretation of clinical imaging
 - Initial focus on CT imaging
- Collect validation sets of de-identified imaging studies curated with clinical reading used in FDA regulatory science assessments
 - CT imaging of patients treated on clinical trials which have led to FDA approvals of drugs
- Make images accessible through consortium to develop tools which can transform imaging assessments

Active Issues for PDS Images and Algorithms Program

- Protection of patient privacy, secondary use consent, etc.
- Attention to highest quality standards and analyses to avoid risks of misleading secondary analyses of existing datasets
- How to structure access to facilitate most effective development of imaging assessment tools
- Linking curated clinical data to imaging time points, with connectivity to validated external readings (by experts)
- Costs of project support

Benefits should be worth the effort

- Current system is suboptimal
- External standards for imaging assessment are sought by FDA to speed effective therapeutic development
- Linking tools to clinically-validated data, with participation of FDA, should accelerate optimal testing and dissemination
- All stakeholders should benefit (especially patients and society)

Thank you all for joining today!

- We look forward to active participation and discussion
- Thanks again to Stanford for hosting
- Everyone is encouraged to think of next-step action items by which we can all work together to move these efforts forward