

June 13, 2015

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 RUSH UNIVERSITY
MEDICAL CENTER

IT'S HOW MEDICINE

SHOULD BE

**Quantitative Imaging Workshop XIII:
Lung Cancer, COPD and Cardiovascular Disease
Exploring the Intersections**

prevent  cancer
FOUNDATION





25 Years of progress through prevention

AND A SPECIAL THANKS ALSO GOES TO THE

WORKSHOP XIII SPONSOR

Carolyn R. “Bo” Aldigé

Prevent Cancer Foundation

STEERING COMMITTEE

Chair:

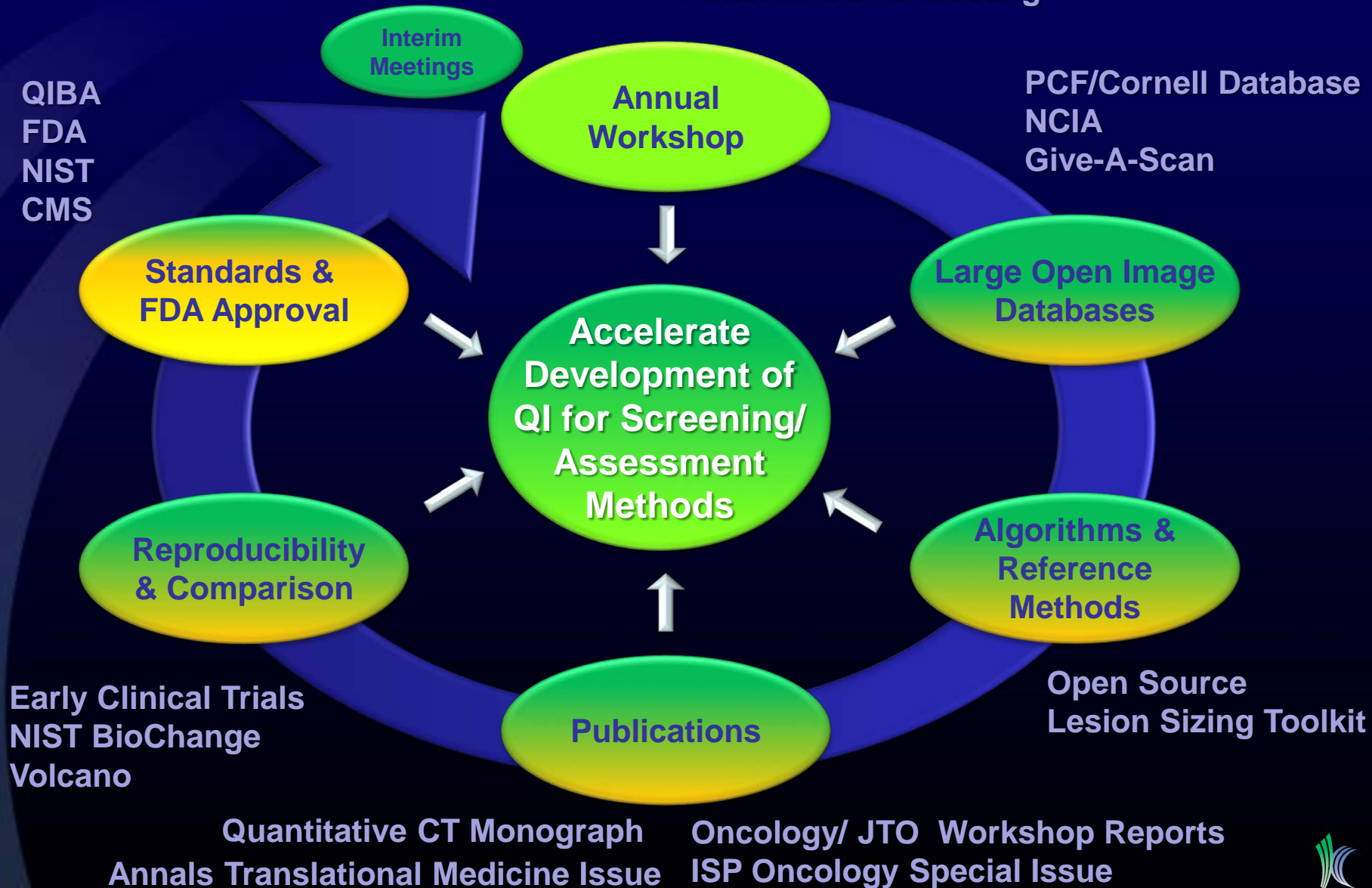
James L Mulshine, *Rush University*

Members:

- Laurie Fenton Ambrose
Lung Cancer Alliance
- Ricardo S. Avila
Accumetra, Inc
- Thomas M. Baer
Stanford Photonics Center/ NPI
- Raul San Jose Estepar
Brigham and Women’s Hospital
- Elisha Malanga
COPD Foundation
- David F. Yankelevitz
Mount Sinai Medical Center

Measuring Progress

13 Workshops since 2004
1 Interim COPD Meeting



- **LDCT lung cancer screening being implemented in US, recommended in Canada and China, not recommended in France**
- **NELSON trial still awaiting final analysis but...**
- **Reports on modeling, cohort selection, screening interval, work up refinements**

QIBA Profile:

Lung Nodule Volume Assessment and Monitoring in Low Dose CT Screening

Version 1.0

Date: May 2, 2016

Status: draft

- ***Document out for public comment***
- ***After reconciliation then work on dissemination***
- ***Aggregate of high quality images to enable regulatory Qualification***

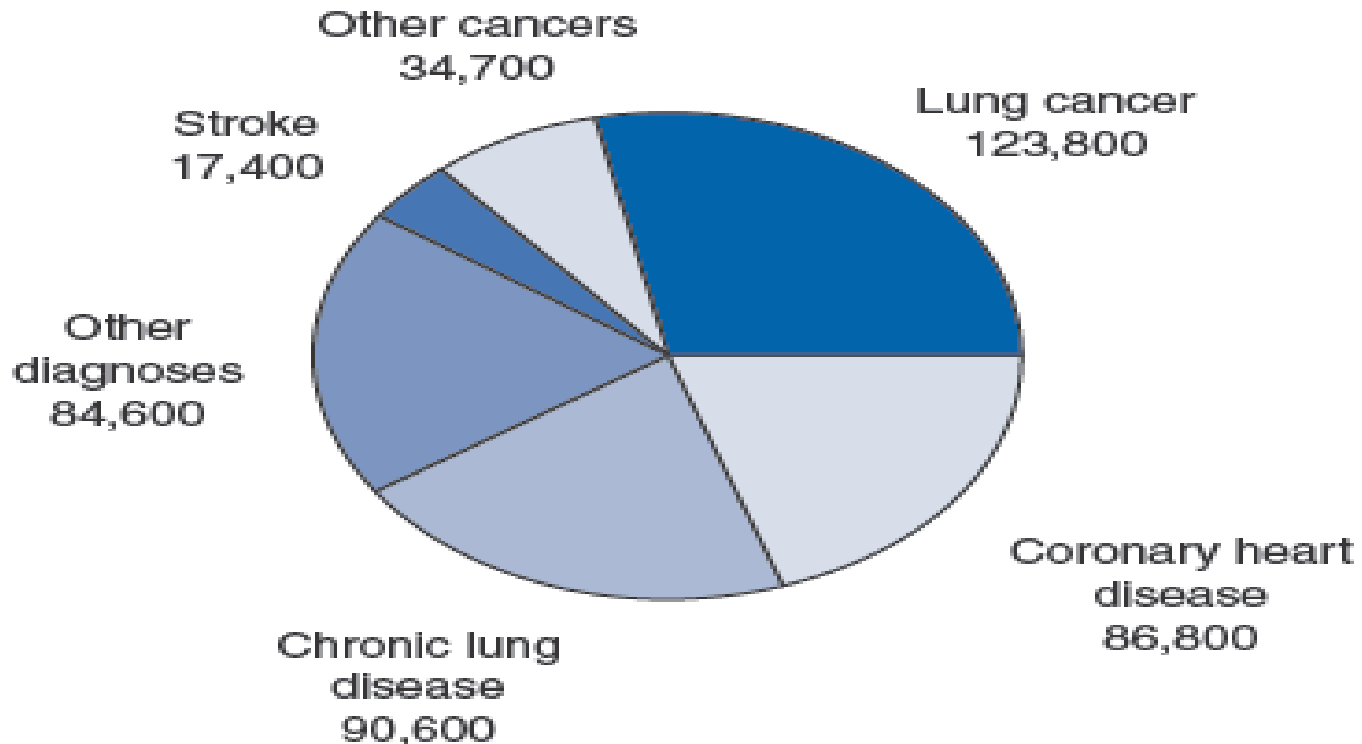


- **Build on the success of our CDRH 2014-2015 Strategic Priorities. These important areas are critical next steps to reaching our vision:**
 - *Establish a National Evaluation System for medical devices;*
 - *Partner with patients*
 - *Promote a culture of quality and organizational excellence.*

- **In collaboration with U of Nebraska Cancer Center, GE, DOD and NCI, a state-wide pilot CT screening project was designed to screen for lung cancer, COPD and CAD to evaluate feasibility**
- **Multiple meetings in Omaha and Bethesda to plan the effort**
- **All collected data was planned to be used as a research resource**

Smoking Deaths and LDCT Screening

**About 438,000 U.S. Deaths Attributable
Each Year to Cigarette Smoking***



* Average annual number of deaths, 1997–2001.
Source: *MMWR* 2005;54(25):625–8.

- Cigarette smoking among adults, 18 & older who smoked 30 cigarettes or more a day went down significantly from 2005 -2012 – from 12.6- 7.0%
- Over 42 million American adults smoke cigarettes. (*CDC, Current cigarette smoking among adults – United States, 2005–2012, 2014*)
- From 2009-2012 US smoking-attributable economic annual costs were \$289-\$332.5 billion including \$132.5 to 175.9 billion for direct medical care of adults. (*US Surgeon General Report 2014*)

How Do You Approach Integrated LDCT Screening for LCA, COPD, CAD (LCC)?

- **From an individuals perspective won't all of this information be overwhelming?**
- **Won't managing LCC be too expensive?**
- **If we are scanning for Lung Ca, will that erode the performance of COPD and CAD detection?**
- **Will saving images of one disease in a clinical/image registry help research related to the other diseases?**
- **What measures would advance this form of research**
- **How to responsibly move from research to public health?**

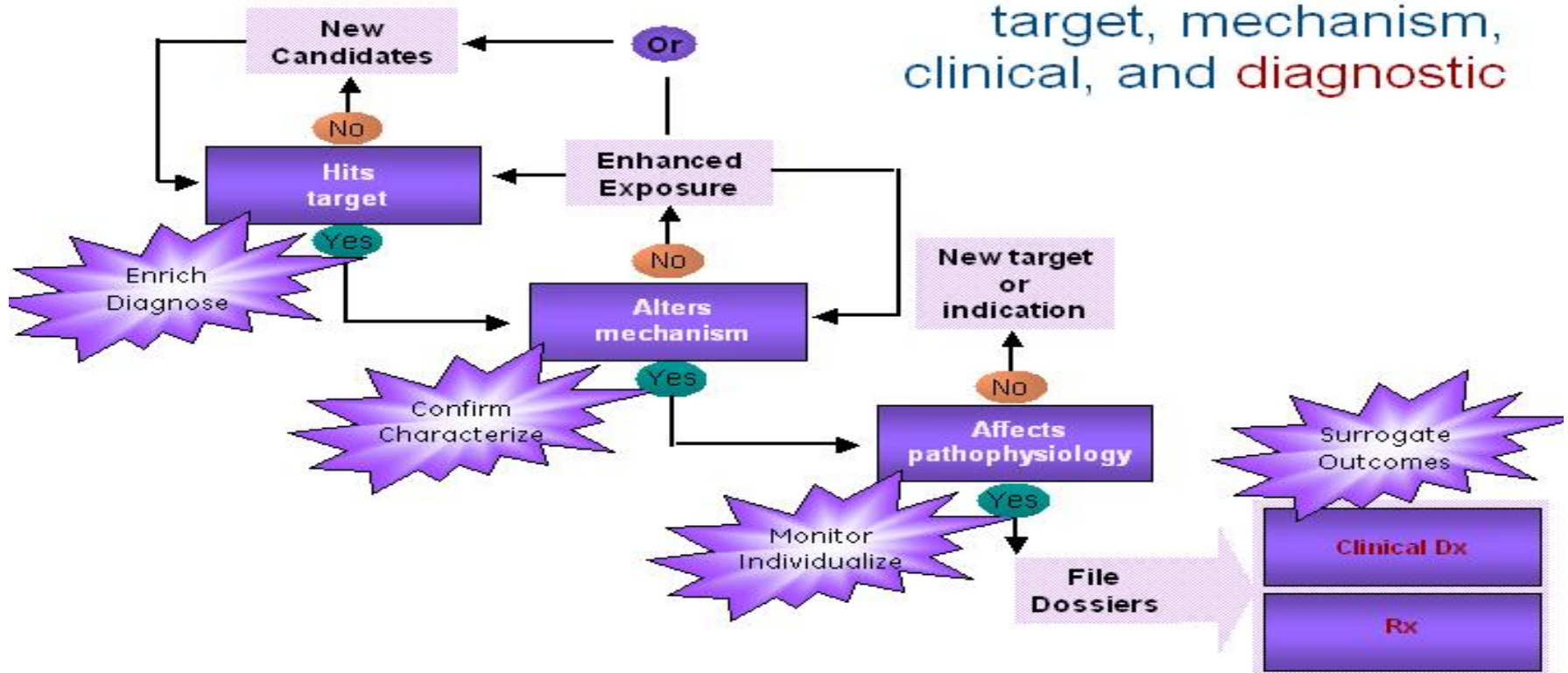
- **Both conditions are diagnosed with advanced disease related to the presence of symptoms**
- **Over time, a number of COPD patients develop Lung CA as well as the reverse**
- **For both, cure is unlikely in late stage disease**
- **CT is a standard tool for both conditions**
- **Companion diagnostics are lacking in managing both conditions**
- **How can we catalyze progress in this area?**

Biomarkers as Endpoints in Clinical Trials of Alzheimer's Disease

Toward an Integrated Academic, Industrial, and Regulatory Perspective

Hampel, Frank, Teipel, Bodke, Hardy, Herholz, Jessen, *Broich (BfArM)*, *Katz (FDA Neuropharm)*, *Sanhai (Senior Scientific Advisor, FDA Commissioner)*, *Woodcock (Director, CDER)*, Zetterberg, Blennow

Biomarker categories:
target, mechanism,
clinical, and diagnostic



- **Insuring high quality, best practices screening process**
- **Making sure of compliance with eligibility criteria and CMS registry and shared decision provisions**
- **Opportunity to enable innovative research in supporting comprehensive data and imaging aggregation registries**

Screening As A Health Encounter

- **Preventive care for major diseases arising from smoking involves significant opportunities for lifestyle changes to reduce risk**
- **LDCT be developed as a normative, quantitative health evaluation tool for high risk, asymptomatic, tobacco-exposed populations (tobacco-injury assessment)?**
- **Annual CT-based tobacco health encounter could bundle coaching on smoking cessation along with other relevant wellness information into an efficient ambulatory prevention encounter focused on addressing major modifiable risk (NCD)**
- **For success need leading professional associations—cancer, pulmonary, nursing & cardiology to collaborate?**

Goal of Workshop

- Identify opportunities or bottlenecks for implementing safe and effective CT based management of early lung cancer and sustaining Continuous Process Improvement
- Ensure the quantitation and methodology are integrated in ways that robust, scalable and economical
- Discuss how to advance thoracic imaging to address the full extent of tobacco injury
- Reframe screening as for tobacco-injury assessment to ensure optimal smoking cessation approaches & for lifestyle changes to reduce risk of premature tobacco-related mortality