Sharing Clinical Trial Data

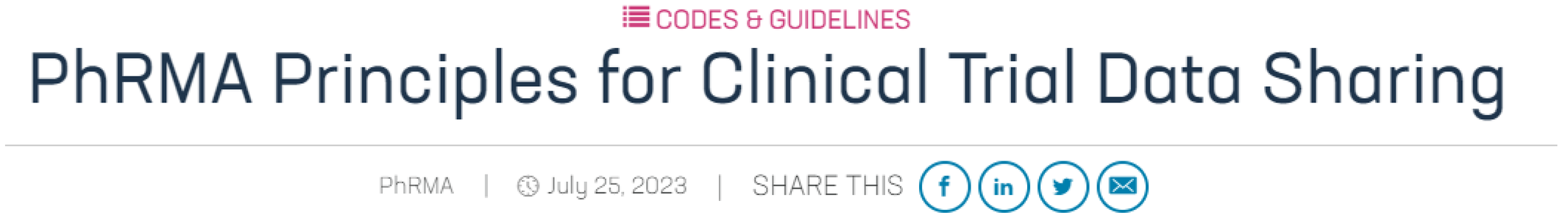
Optimizing Public-Private Partnerships for Clinical Cancer Research

October 17-18 | National Cancer Policy Forum

Geoffrey R. Oxnard, MD
VP, Clinical Development | Global Development Lead, Thoracic Cancers
Loxo Oncology @ Lilly

Sharing clinical trial data

- Clinical trial data sharing is routine and an industry standard



Data sharing comes in various flavors depending on the exact mechanism:

1. Clinical trial registry data posting
2. Individual patient-level data sharing
3. Precompetitive public-private partnerships

https://phrma.org/resource-center/Topics/Clinical-Trials/PhRMA-Principles-for-Clinical-Trial-Data-Sharing

Geoff Oxnard, MD
Loxo Oncology @ Lilly

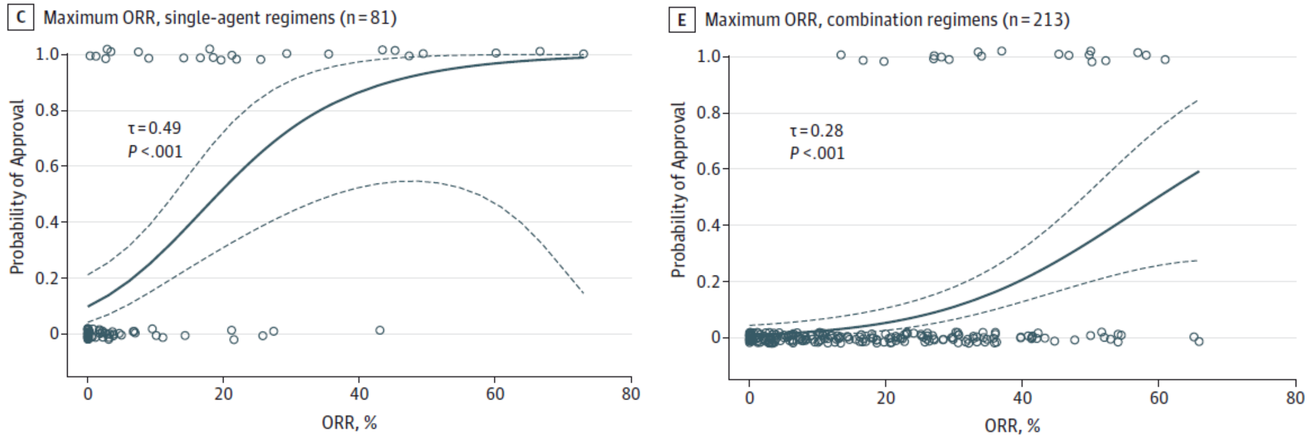
Clinical trial registry data posting

- Trial registry is required broadly by regulators, journals and industry standards
- Such databases of trial results can enable limited trial-level meta-analysis

Original Investigation

Response Rate as a Regulatory End Point in Single-Arm Studies of Advanced Solid Tumors

Geoffrey R. Oxnard, MD; Katharine H. Wilcox, BA; Mithat Gonen, PhD; Mikhael Polotsky, MD; Bradford R. Hirsch, MD; Lawrence H. Schwartz, MD



Invited Commentary

June 2016

Response Rate as an Approval End Point in Oncology

Back to the Future

Gideon M. Blumenthal, MD[1]; Richard Pazdur, MD[1]

LOXO @ Lilly

Oxnard et al, JAMA Onc, 2016; Blumenthal & Pazdur, JAMA Onc, 2016

Geoff Oxnard, MD
Loxo Oncology @ Lilly

Individual patient-level data sharing

- Individual patient-level data sharing (IPD) for clinical trials is routine for many sponsors, generally following publication:

Lilly provides access to all individual participant data collected during the trial, after anonymization, with the exception of pharmacokinetic or genetic data. Data are available to request 6 months after the indication studied has been approved in the US and EU and after primary publication acceptance, whichever is later. No expiration date of data requests is currently set once data are made available. Access is provided after a proposal has been approved by an independent review committee identified for this purpose and after receipt of a signed data sharing agreement. Data and documents, including the study protocol, statistical analysis plan, clinical study report, blank or annotated case report forms, will be provided in a secure data sharing environment. For details on submitting a request, see the instructions provided at www.vivli.org.

- Between 2014-2022:
  - 440 studies available for request
  - 146 proposals received
  - 94 proposals with data provided
  - 42 publications/presentations

Open Access Article

Using the Systemic Immune-Inflammation Index (SII) as a Mid-Treatment Marker for Survival among Patients with Stage-III Locally Advanced Non-Small Cell Lung Cancer (NSCLC)

by Tithi Biswas [1], Kylie H. Kang [2], Rohin Gawdi [3], David Bajor [4], Mitchell Machtay [5], Charu Jindal [6] and Jimmy T. Efird [7,*]

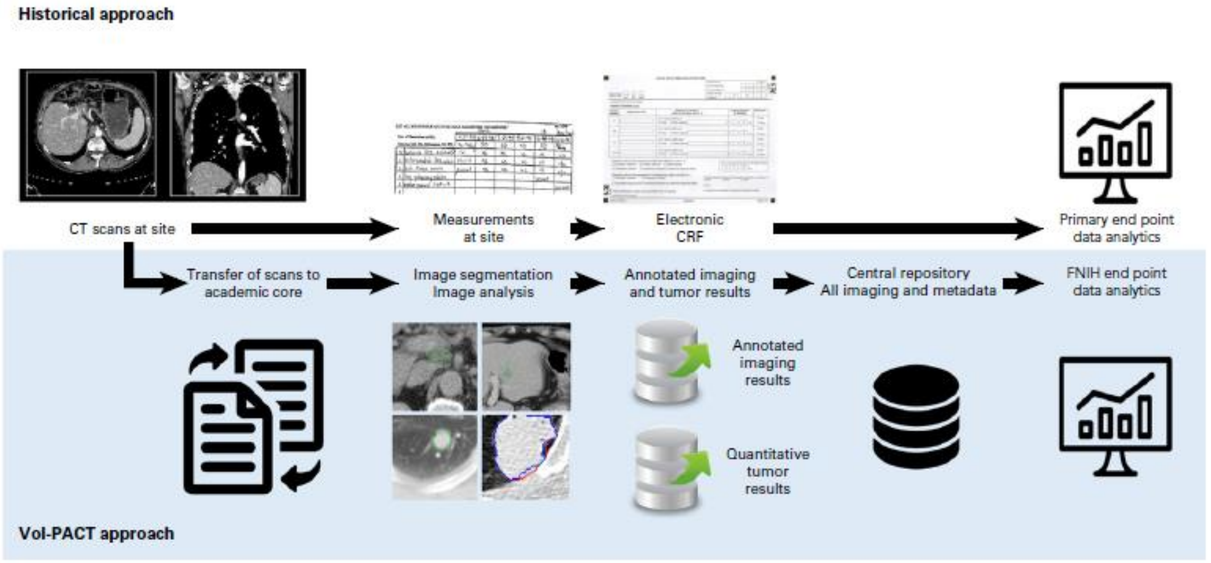
Biswas et al, IJERPH, 2020

Geoff Oxnard, MD
Loxo Oncology @ Lilly

Precompetitive public-private partnerships

- Precompetitive efforts (FNIH, FOCR, Project Datasphere, etc) are a powerful mechanism for collaborative analysis of trials from multiple sponsors

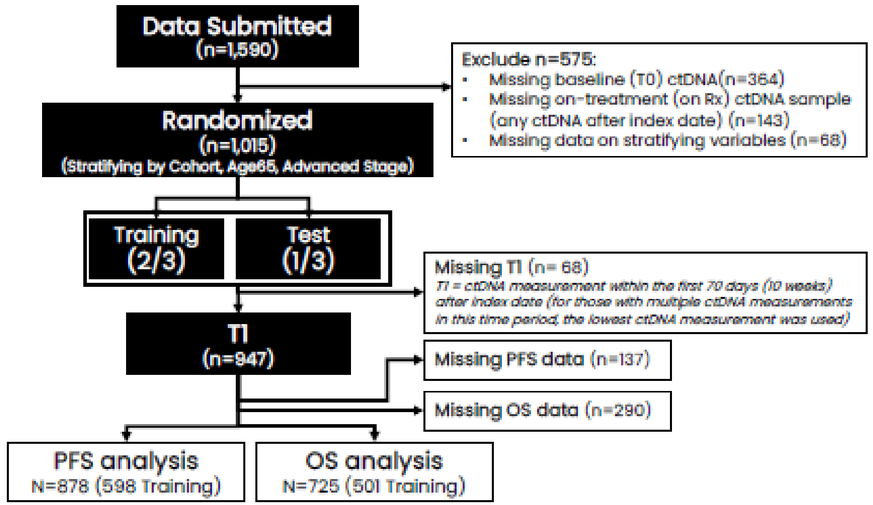
Biomarkers Consortium – Vol-PACT: Advanced metrics and modeling with Volumetric CT for Precision Analysis of Clinical Trial results



ctMoniTR Project

ctDNA for Monitoring Treatment Response Project

CONSORT Diagram & Patient/Assay Characteristics



Dercle et al, JCO-CCI, 2018; Stires et al, ASCO, 2023

Geoff Oxnard, MD
Loxo Oncology @ Lilly