RWD Forum 2023
Moving Forward Together

Real-World Evidence as the centerpiece for the evaluation of LungFlag pre-screening digital algorithm

Yue Jin[1], Milan Obradovic[2], Eva Flahavan[3], Nicolò Olghi[4], Thanh G.N. Ton[3]

[1]Roche Diagnostics, RIS, Real-World Data; [2]Roche Pharma, PDMA Oncology; [3] Roche Pharma, PDD Real-World Data Science; [4] Roche Pharma, PHC PD Digital Health

33

BACKGROUND

The burden and mortality of lung cancer has been clearly quantified worldwide. Despite this, no country has established a nationwide lung cancer (LC) screening program. In the United States (US), although the US Preventive Services Task Force (USPSTF) recommends LC screening by low-dose computed tomography (LDCT) in high-risk individuals, compliance to these guidelines remains poor. A personalized risk score may help increase compliance to LC screening. Roche is generating clinical and operational evidence to support the global strategic commercialization of a third-party (MedialEarly Signs) digital algorithm using data from electronic health records that may help to increase compliance of high-risk individuals to LDCT. Central to the evidence generation strategy are real-world data (RWD) studies from multiple countries across global Pharma-Dia and affiliate groups.

METHODS

A total of 8 RWD studies and 4 operational pilots have been planned or completed using RWD representing routine clinical practice and observational methods to develop an overarching strategy to validate and evaluate the use of LungFlag in local systems.

Evidence generation based solely on Real-world Data

RWD retrospective validation studies → **RWD studies in local market** → **RWD Operational pilot studies**

US
LungFlag was recently replicated using Optum Market Clarity in a **case-control study design**.

UK
A study is underway to validate the LungFlag using United Kingdom's Clinical Practice Research Datalink (CPRD) in a population-based **retrospective cohort design**.

Local Affiliates
To further assess the relevance of LungFlag in local markets, Roche affiliates including **Taiwan**, **Denmark**, **Australia**, **Estonia**, **Canada** have proposed studies using **local RWD**.

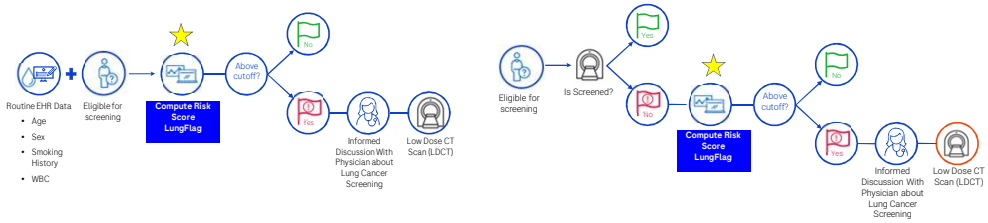
US (Geisinger)
A separate **observational RWD study** is planned at Geisinger.

Operational Pilots
Pilots evaluating the operational implementation of LungFlag are being discussed in **Denmark**, **Spain**, **Brazil** and in the **US (Geisinger)**.

LungFlag Workflow: Digital biomarker to rule-in high risk patients

For all eligible patients: improving efficiency of screening programs

For eligible patients who are non-compliant: personalized results to non-compliant patients



LungFlag Value Proposition

A ML/AI-developed algorithm to enrich the lung cancer screening (LCS) population by identifying high-risk patients

Improves LCS programs	Performance	Flexible cut-off	Personalized results	Limited set of parameters
By enriching the eligible population, LungFlag makes Lung Cancer screening initiatives more efficient Additionally, can act as safety net for non compliant patients to be encouraged to get screened	LungFlag outperforms PLCOm2012, the most studied pre-screening Algo LungFlag shows great performance in Early Stages	LungFlag offers providers the possibility to adjust the cut-off based on the capacity of the system to screen patients	LungFlag provides a personalized risk results that may increase patients compliance to follow up procedures	With age, sex, smoking history and WBC, LungFlag requires a limited set of mandatory parameters to provide a personalized result

IMPACT

As one of the first PHC algorithms on the cusp of commercialization for Roche, **LungFlag has relied exclusively on RWE (e.g., no RCTs) as the cornerstone of evidence generation from development stages to validation and implementation**, while incorporating new global and local processes for RWD studies conducted within Roche.

QR code

Roche