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Multi-site collaboration initiative: example of I-O Optimise

I-O Optimise Programme Overview

What is I-O Optimise?

I-O Optimise is an ongoing collaborative real-world research initiative focused on building a…

...**first of its kind multinational real-world platform** that leverages existing real-world data sources to provide ongoing, timely, and novel evidence into…

…**real-world treatment patterns and outcomes** in patients with lung cancer in Europe and Canada.

Guided by a multidisciplinary scientific committee comprised of clinical and research experts…

...**I-O Optimise is generating real-world insights and evidence** that support a broad range of healthcare stakeholders in their efforts to transform patient care in non-small cell lung cancer and mesothelioma…

…**with the collective goal of improving patient outcomes in lung cancer.**

I-O optimise is collaborating with multiple organisations across Europe and Canada

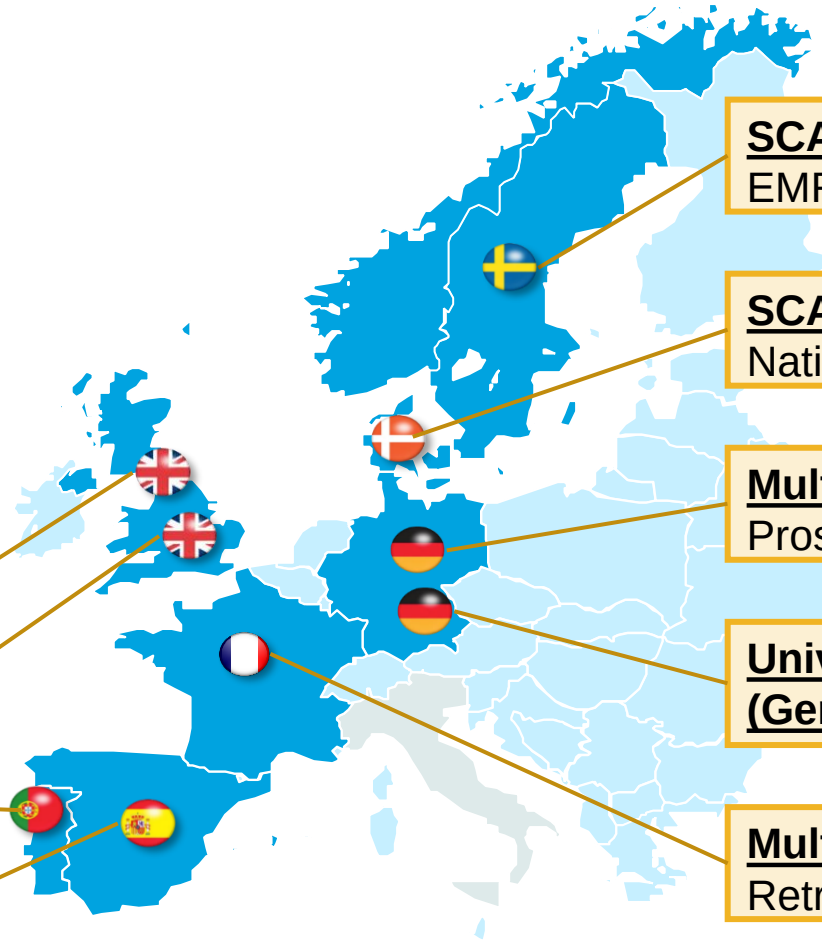
Alberta (Canada):
Multi-source database

REAL-Oncology (UK): EMR

CAS (UK): National cancer database

IPO-Porto (Portugal): EMR & registry

Multi-centre (Spain):
Prospective multicentre cohort study



SCAN-LEAF (Sweden): Multiple EMR and national registries

SCAN-LEAF (Denmark):
National registries

Multi-center (Germany):
Prospective NSCLC cohort study

University of Frankfurt (Germany): EMR

Multi-center (France):
Retrospective Lung cohort study

Three key stakeholders for I-O Optimise

STEERING COMMITTEE

Help guide the overall scientific strategy of the research initiative and contribute to research planning and general Consortium engagement

DATA SOURCES

Provide access to data and collaborate on planned analyses and share knowledge and formulate best practice with RWE generation

PATIENT VOICE

Provide the patient’s perspective and guidance on how to leverage RWE to support patient access and policy change within Europe

The External Scientific Committee guides the scientific agenda and research objectives of I-O Optimise

 **Paul Baas**	 **Mariano Provencio**	 **Christos Chouaid**	 **Isabelle Durand-Zaleski**	 **Simon Ekman**	 **Søren Paaske Johnsen**	 **Frank Griesinger**
Physician, Chief of Department of Thoracic Oncology, Netherlands Cancer Institute, Netherlands	Physician, Head of Medical Oncology Department, Hospital Universitario Puerta de Hierro-Majadahonda, Madrid, Spain	Physician, Head of Department of Pneumology and Thoracic Oncology, Créteil, France	Health Economist, Professor in Public Health, Paris Health Economics and Health Services Research Unit, Paris, France	Physician, Senior Consultant and Associate Professor in Oncology, Karolinska University Hospital, Stockholm, Sweden	Research Consultant, Associate Professor of Epidemiology, Aarhus University Hospital, Denmark	Physician, Director of Department of Haematology and Oncology, Pius-Hospital Oldenburg, Germany

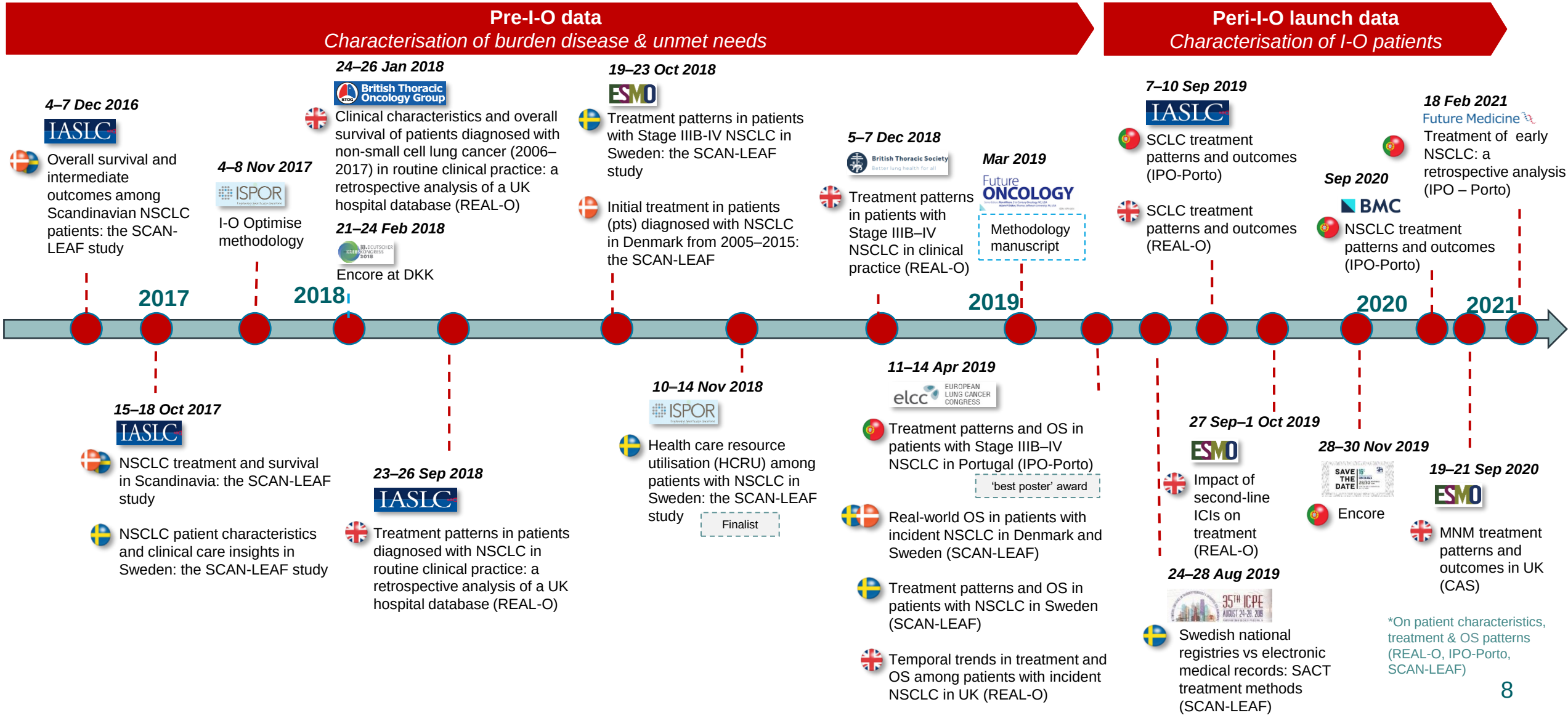
I-O Optimise is generating ongoing scientific insights into lung cancer and mesothelioma treatment and outcomes

Research priorities	Description
Clinical outcomes	▪ Describe clinical and patient characteristics ▪ Understand **real-world effectiveness** of lung cancer treatments ▪ Investigate impact of alternative treatment patterns on clinical outcomes ▪ Explore **patient subpopulations** and associated outcomes
Treatment patterns	▪ Explore context for usage and duration of immuno-oncology (I-O) therapy treatment ▪ **Biomarker testing flow** and role in I-O lung cancer treatment decisions ▪ Document current and emerging lung cancer clinical care pathway and treatment patterns
Frequency of Adverse Events (AEs)	▪ Understand the frequency and management of AEs for different treatments and for different patient sub-groups ▪ Evaluate how AEs impact **treatment duration**
Health resource utilisation	▪ Understand costs of treatment, care and patient management ▪ **Assess economic value** of lung cancer treatments, specifically I-O therapies
Patient reported outcomes	▪ Explore lung cancer **patient quality of life** ▪ Understand physical and psychological impact on patients

Research to date has focused on characterisation of disease, treatment patterns, and clinical outcomes in NSCLC

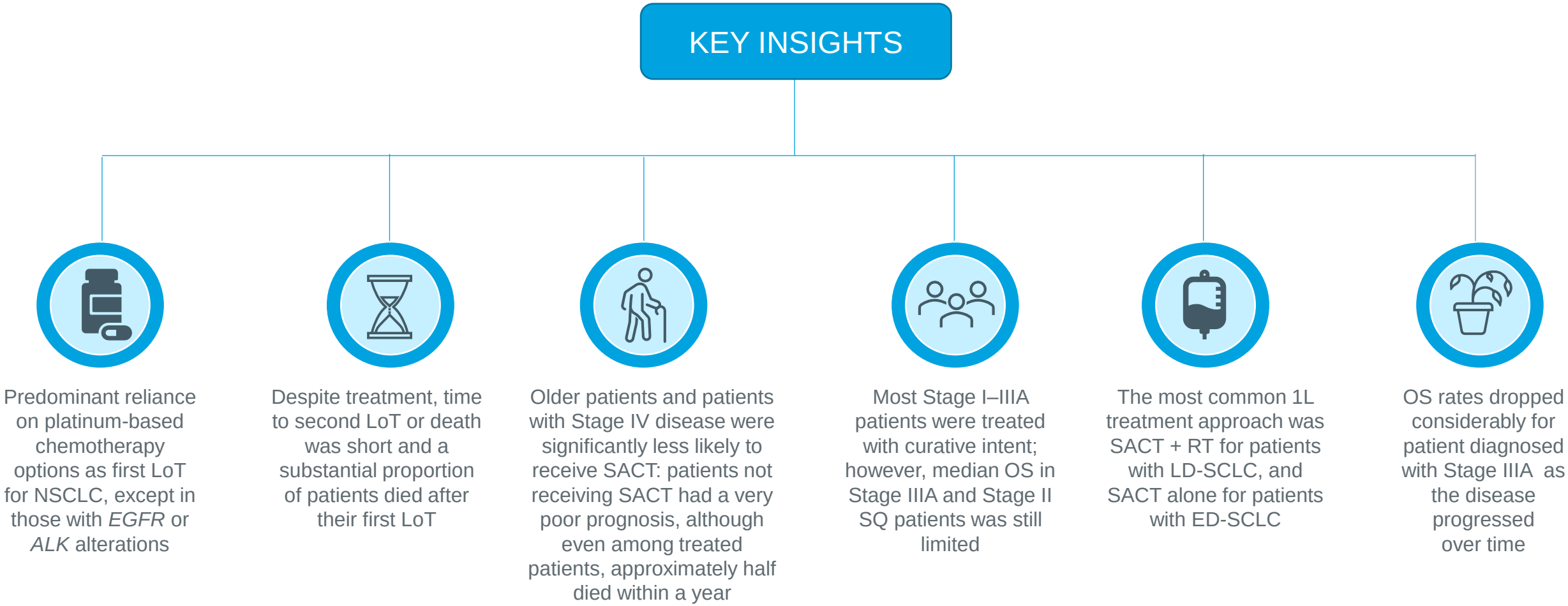
Indication	Study Cohort	Priority Research Topics
NSCLC	**Early Stage** *Stage I-IIIA*	• Initial and subsequent treatments • Characterisation of neo/adjuvant treated patients • Characterisation of 'resectable / non-resectable' patients • Describe transition from locally advanced disease to metastatic disease
	Advanced Stage *Stage IIIB-IV*	• Describing changes in clinical practice since I-O introduction • 2L I-O experience • Optimal chemo-I-O sequencing for patient sub-populations including I-O responders and non-responders
Malignant Pleural Mesothelioma	**Advanced MPM**	• Epidemiology • Patterns of care – treatment rates, use of SoC / chemo • Outcomes and limitations of current SoC

I-O Optimise publications have focussed on characterising the burden of disease and patients receiving I-O therapies



*On patient characteristics, treatment & OS patterns (REAL-O, IPO-Porto, SCAN-LEAF)

REAL Oncology: Publication Summary



ED, extensive disease; LD, limited disease; LoT, line of therapy; MPM; malignant pleural mesothelioma; NSCLC, non-small cell lung cancer; OS, overall survival; SACT, systematic anti-cancer therapy; SCLC; small cell lung cancer; SoC, standard of care, SQ, squamous.

I-O Optimise Collaboration: data partners' perspective

There are multiple benefits to collaborating with I-O Optimise

Platform aims	Potential benefits for collaborators
High quality data	▪ Investment in data to increase data quality and completeness ▪ Standardisation of data for increased interpretability of results from studies ▪ Opportunity for enhancement, research in compliance with GDPR ▪ An established data infrastructure for further research purposes
High impact research	▪ Publication opportunities for disease area research across thoracic malignancies ▪ Presentations at international conferences ▪ Opportunity to be a part of a major RWE programme for understanding the treatment of lung cancer
Build relationships & gather expertise to strengthen the science	▪ Work with leading experts in the field of lung cancer and immuno-oncology ▪ Collaborative data analysis and data management with BMS and IQVIA ▪ Opportunity to build relationships with academics across Europe
Functional collaboration	▪ Non-exclusive collaboration ▪ Independence: retention of original data rights

The Research Collaboration Model has three components, and is designed to be flexible

Research Collaboration

- You will have input to initial shape research questions and plans
- You will be involved in end-to end research execution
- You will be co-authors on related publications

Types of data

- Leverage existing retrospective / secondary EMR data sources
- High quality data that describes the patient characteristics, treatment patterns, clinical characteristics, patient outcomes, safety, biomarkers, and healthcare resource utilization
- Only aggregated outputs from research partners are released as the analysis is performed on-site

Information Governance

- IQVIA will adhere to local as well as European Information Governance regulations.
- Patient level data does not have to be transferred to IQVIA

Reimbursement

- Support from I-O Optimise follows fair market value regulations and is made for
  - Extraction, curation, QA and enhancement of the data
  - 3rd party analysis of data
  - Reimbursement is offered for participation in BMS sponsored meetings
- Authorship activities are not reimbursed

Summary of desired variables for I-O Optimise research

Themes	Summary of variables
Patients characteristics	• Year of birth, Gender, Weight, Height, BMI, Ethnicity, Smoking Status etc
OS	• Date of death; Cause of death
Clinical Characteristics	• Patient diagnosis date, follow up time, Histology, Diagnostic Procedure, Evaluation of tumour staging captured at diagnosis • TMN staging, grade of tumour, size of tumour, Number of metastatic organ sites at time of diagnosis etc.
Biomarkers	• Date biomarker of test • PDL-1 test date and result; EGFR test date and result; ALK test date and result; ROS test date and result etc • PDL-1 expression level
Treatment characteristics	• Treatment start and end date • Systemic Anti Cancer Treatment (SACT), SACT dosage surgery and radiotherapy captured etc
Other effectiveness	• Treatment response, Tumour response, Disease progression, Date of relapse etc
Safety	• Adverse events related to line of therapy; date of adverse events, impact of adverse event on treatment; Toxicity
HRQoL	• Patient satisfaction, Patient well-being, Pain, QPAL-GM, Activities daily living, WPAI-GH, etc
HCRU	• Total length of stay, Number of emergency visits, number of outpatient visits, Surgical interventions etc

Not all variables are required at every data source, but these are representative of the research questions within I-O Optimise

Summary

With basic structured disease data in place, academic centres can join meaningful multi-country RWE research programmes, with research getting more ambitious as the data improves

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Thank you for your attention!