Learning & Improve Professional Skills (LIPS) Track - Session 7
Oncology & Theranostics + Translational Molecular Imaging & Therapy Committee / European Organisation for Research and Treatment of Cancer (EORTC)
Monday, October 17, 15:00-16:30

Session Title
Setting Up and Managing Imaging Trials

Chairpersons
Christophe Deroose (Leuven, Belgium)
Karolien Goffin (Leuven, Belgium)

Programme

15:00 - 15:30 **Saskia Litière** (Brussels, Belgium / EORTC): Challenges of Introducing Imaging Biomarkers as End-Points into Clinical Trials

15:30 – 16:00 **Marion Smits** (Rotterdam, Netherlands): How do I share my Trial Data?

16:00 – 16:30 **Luc Bidaut** (Lincoln, United Kingdom): What is the Shelf-Life of Imaging Data?

Educational Objectives

1) To understand the requirements for a methodological validation of an imaging based end-point in clinical trials
2) To be aware of practical limitations of the implementation of imaging in clinical trials
3) To understand the importance and limitations of trial data sharing
4) Knowledge about how to set up trial data sharing
5) To understand issues that might arise and affect imaging data retrieval and future use and their mitigation strategies.

Summary

Imaging plays a very important role in different aspects of clinical trials, from staging the disease to monitoring the response of patients to treatment. Currently a lot of research is ongoing in the field of radiomics to automate segmentation and facilitate assessment of response to treatment beyond the current standards such as RECIST. However, like other trial endpoints, imaging biomarkers need to be objectively measurable, reproducible and there needs to be evidence of an association with a true patient benefit endpoint for it to be used as an early biomarker of treatment effect. In this session we will cover some of the challenges this implies specifically to imaging endpoints.

Sharing data is an essential part of open science and contributes to research integrity, reproducibility, and progress. The sharing of imaging data comes with specific challenges such as related to the size of the data and privacy issues. In this session we will address these challenges and provide recommendations for overcoming these.

“Good data” are the ones that can be properly retrieved and used. For clinical trials, data of different kinds need to be collected, collated, retrieved and eventually analysed, not only for the primarily intended

purpose, but also - ideally and because such data are so scarce and/or expensive to produce - for subsequent applications that might not have been initially foreseen. In this session, we will go over some of the rationale, challenges and succinct recommendations about why and how best to extend the relevant lifespan of collected data and images.

Key Words
Surrogate endpoint, Phase II/III clinical trial, RECIST, Standardization, MRI, Brain Tumour, Oncology, Clinical trial data, Data storage, Data retrieval, Data lifespan