DigiCore

IDEAL4RWE

***Immunotherapy in recurrent/metastatic head and neck cancer**: real-world data from six European countries (2017-2022)*

November 7/8, 2022

The Digital Institute for Cancer Outcomes Research

Immunotherapy in patients with recurrent or metastatic HNSCC

- Are we treating the same patients?
- Are we using the same treatment approach?
- Are we using immunotherapy in the same way, and do we observe the same irAE?

Research Questions

What are the characteristics of this RW patient cohort?

What are the types and timing of treatments preceding and following immunotherapy in this RW patient cohort?

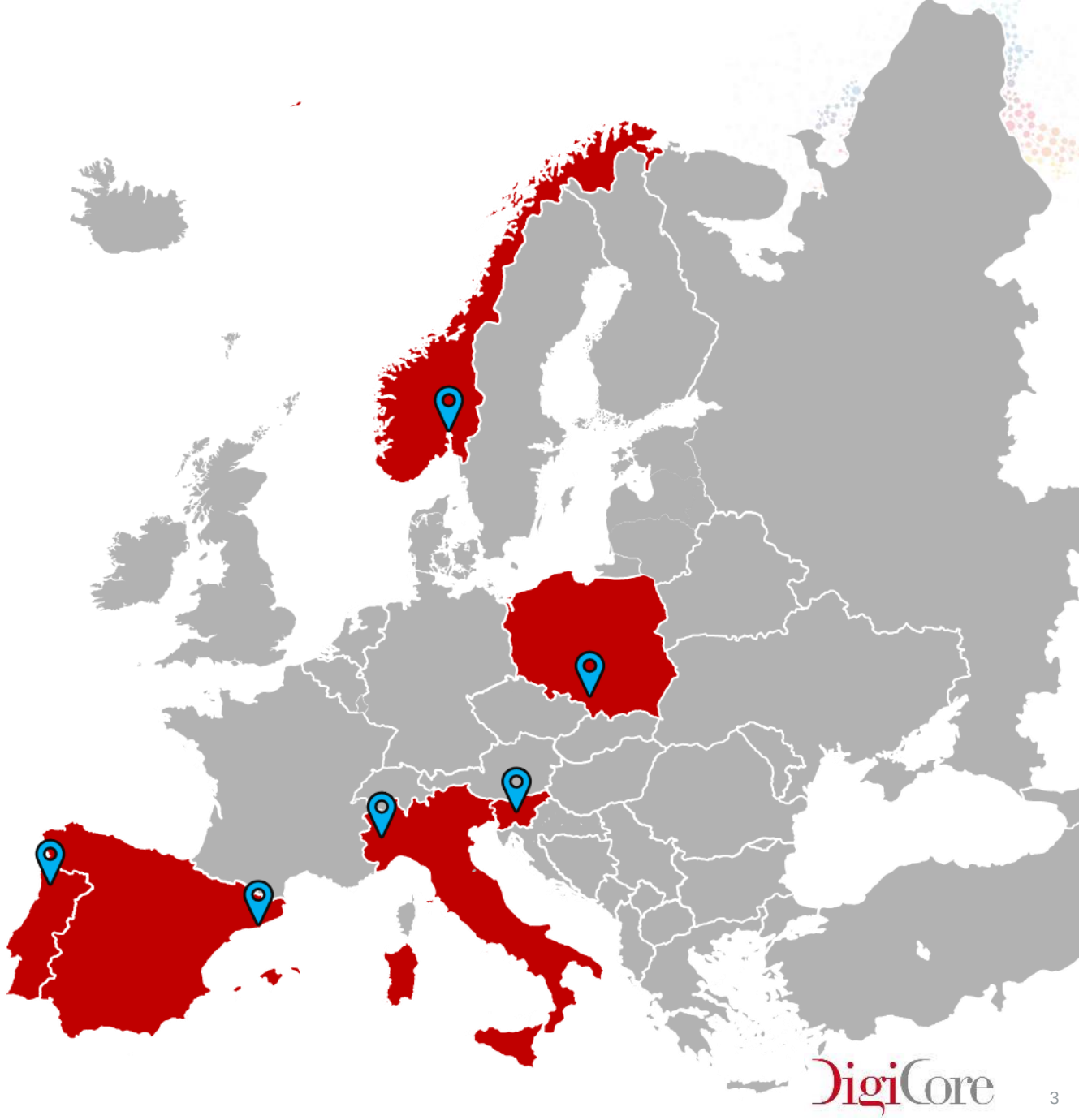
What are the details and schedule of immunotherapy and the irAEs in this RW patient cohort?

- What is the **effectiveness** (OS, rwPFS, TTNT, TTD) of immunotherapy in **this cohort of patients**?
  - What is the **effectiveness according to the stratification** factors?
- **Are TTD and TTNT comparable to rwPFS in R/M HNSCC** and can be used as surrogates in future RWE research?

Participating sites

Immunotherapy in patients with recurrent or metastatic HNSCC

- **Slovenia**
  - Institute of Oncology Ljubljana
- **Portugal**
  - Instituto Português de Oncologia do Porto Francisco Gentil
- **Norway**
  - Oslo University Hospital
- **Italy**
  - San Luigi Gonzaga Hospital and Mauriziano Umberto I Hospital, University of Turin
- **Spain**
  - Vall d´Hebron Institute of Oncology / University Hospital Vall d´Hebron, Barcelona
- **Poland**
  - Maria Sklodowska-Curie National Research Institute of Oncology in Gliwice



Patient Cohort

INCLUSION CRITERIA

- Recurrent/metastatic squamous cell carcinoma of the head and neck patients who have received therapy with anti-PD-1 monoclonal antibodies for advanced disease.
- Initiation of immunotherapy from 1st March 2017 to 1st May 2022.
- ≥ 18-year-old at diagnosis
- Availability of the date of treatment initiation and disease progression and/or patient death, whichever occurred first.

EXCLUSION CRITERIA

- Other invasive cancer in the time period of 5 years before IT and up to the end of follow-up, except for basal cell carcinoma of skin
- Treatment with anti-PD-1 immunotherapy combined with other non-standard immunotherapies
- Incomplete treatment data

Patient Cohort

~530 patients

Multicenter retrospective real-world data analysis

~100 patients	~80 patients	~21 patients	~100 patients	~80 patients	~150 patients
					
Portugal	**Spain**	**Italy**	**Slovenia**	**Norway**	**Poland**
Instituto Português de Oncologia do Porto Francisco Gentil	Vall d´Hebron Institute of Oncology / University Hospital Vall d´Hebron, Barcelona	San Luigi Gonzaga Hospital and Mauriziano Umberto I Hospital, University of Turin	Institute of Oncology Ljubljana	Oslo University Hospital	Maria Sklodowska-Curie National Research Institute of Oncology in Gliwice

Patient Cohort

~530 patients

Baseline period start date: **date of diagnosis**

Index Date (ID)
PD1 first infusion

Cut-off Date
15 Nov 2022

Baseline period

Minimum 6 months follow-up post ID

INDEX PERIOD

1st March 2017 — 1st May 2022

Methodology

~530 patients

Data collection at each collaborating Centre

General Patient Characteristics

Patient characteristics at Immunotherapy initiation

Treatments

Follow-up

Transfer of aggregated data to IPO

Only aggregated data/results will be transferred

Publication of the results

ESMO 2023

ICHNO

Scientific paper

Based on a R software script shared across sites

Time-dependent outcomes (rwPFS, TTNT, OS, TTD)

Descriptive analysis of cohort

Data Analysis at each collaborating Centre

Comparing between/within countries

Meta-analysis

Description of the findings and revision of data

Opportunities & Challenges

Networking

- Exchanging clinical and research experience with peers and discussing open questions within this diverse team
- Good basis for future research collaboration
- Open to develop

This **research group includes six nations & can be easily expanded** by inclusion of additional research centres in the future

- The starting group was already expanded to include The Maria Sklodowska-Curie National Research Institute of Oncology from Gliwice, Poland

Challenges

- Expertise in RWE research (e.g. statistical analyses)
- Structured data (a lot of manual extraction still needed across the centres)
- Available data (differences in EMR in different hospitals)
- Comparability across sites (differences in drugs reimbursements, differences in requirements of ethical committees...)
- Distance & Time (even dedicated time for research at workplace can be interrupted by clinical call)