Conceptualization of core clinico-molecular variables for registries enrolling patients diagnosed with a solid tumor and profiled with next-generation sequencing (NGS)

5246

Rodrigo Dienstmann, Clare Turnbull, Allan Hackshaw, Jean-Yves Blay, Maud Kamal, Nicolas Servant, Jan Geissler, David Tamborero, Janick Weberpals, Simon Fear, Camille Perret, Laura Perez, Martina von Meyenn, Christophe Le Tourneau

Supplement: Full variables list

Please see:
https://ter.li/lkb1mi

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Supplement: Optional variables to be included and recommendations for vocabularies

Patient

BMI

SES* (e.g. education, employment, occupation)

Critical comorbidities impacting outcome (e.g. using CCI)

Previous cancer(s)

Cancer

Basis of diagnosis

MTB recommendations

Physician decisions (e.g. referral to MTB and treatment)

NGS testing

Lab details (e.g. certification)

Details of commercial and non-commercial tests

Sampling details (e.g. date of sampling and results, tumor event)

NGS test wet and dry details, quality, and results

Tumor/treatment characteristics

Whether CNS metastases are present (yes/no)

Number of metastatic sites

List of diagnostic procedures

Treatment recommendations

Means of access to treatment

Outcomes

Primary cause of death

These variables may be prioritized based on study objectives. They are of value because they help assess the quality of the NGS test performed to select the population, enhance confidence in RWD comparative analyses and generate results that are more reliable (with adjustment of confounders), explore research questions related to NGS/treatment access and understand how diagnosis is performed in clinical practice, and understand the clinical utility of MTBs and their impact on the patient journey.

*As part of epidemiologic research, socioeconomic data (including race, nationality, SES, comorbidities such as diabetes, cardiovascular disease, bacterial and viral infections, family history of cancers, previous cancers, and reproductive status) are often only poorly reported in medical records although essential for understanding the patient disease context. Socioeconomic data have been associated with cancer incidence and/or outcomes and enable production of adjusted statistical estimates that are reliable and representative of the disease context. Failure to collect this information reduces the usability of the dataset, and its scientific purpose may not be met.[1]

Recommendations for vocabularies

Disease: ICD-O-3 (3rd edition)

Past cancers/family history: Short code list derived from ICD10

Drug names: ATC (September 2020)

Genomic results: HGVS

Procedures: Short code list from CDISC

Safety: MedDRA (v23.1)

Clinical response: WHO, mRECIST vX, PERCIST vX, etc.

Performance status: ECOG (or Karnofsky)

Comorbidities: e.g. ICD9/10, CCI, ACE-27, SCQ

Recommendations are aligned with EMA registry guidelines (October 2021).[2] Using standard vocabularies will ensure capture of clinical events is performed in a consistent manner, allowing pooling from disparate sources, to produce meaningfully comparable and reproducible results.

Abbreviations

ACE, Adult Comorbidity Evaluation; ATC, Anatomical Therapeutic Chemical; BMI, body mass index; CCI, Charlson Comorbidity Index; CDISC, Clinical Data Interchange Standards Consortium; CNS, central nervous system; ECOG, Eastern Cooperative Oncology Group; EMA, European Medicines Agency; HGVS, Human Genome Variation Society; ICD-O-3, International Classification of Diseases for Oncology, 3rd Edition; ICD9/10, 9th/10th revision of the International Classification of Diseases; MedDRA, Medical Dictionary for Regulatory Activities; (m)RECIST, (modified) Response Evaluation Criteria in Solid Tumors; MTB, molecular tumor board; NGS, next-generation sequencing; PERCIST, Positron Emission Tomography Response Criteria in Solid Tumors; RWD, real-world data; SCQ, self-administered comorbidity questionnaire; SES, socioeconomic status; WHO, World Health Organization.

Reference: 1. Public Policy Committee, International Society of Pharmacoepidemiology. *Pharmacoepidemiol Drug Saf* 2015. 25:2–10; 2. EMA. Guideline on registry-based studies. October 22, 2021.

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Supplement: Conflicts of interest

RD is an employee of Oncoclínicas Grupo, has business ownership in Trialing, has received a grant/contract from Merck, has performed a consulting/advisory role for Roche and Boehringer Ingelheim, and has attended speakers' bureaus for Roche, Ipsen, Sanofi, MSD Oncology, Servier, Amgen, and Libbs. **CT** has received honoraria from AstraZeneca, Pfizer, and Roche, has performed a consulting/advisory role for AstraZeneca and Roche, and has attended a speaker's bureau for AstraZeneca. **AH** has held stock in Illumina and ThermoFisher (sold in 2020), has received grants/contracts from Roche, MSD, Takeda, BMS, Boehringer Ingelheim, and Celgene (several pharmaceutical companies provided research funding for UCL-sponsored trials), has received honoraria from AbbVie, Boehringer Ingelheim, Takeda, AstraZeneca, Daiichi Sankyo, Merck Serono, Merck/MSD, UCB, and Roche for delivering general education/training in clinical trials, and has performed a consulting/advisory role for AbbVie, Roche, and GRAIL, Inc. **J-YB** has received grants/contracts from Novartis, Bayer, GSK, Pfizer, Deciphera, Roche, BMS, MSD, and AstraZeneca, has a leadership role with Innate Pharma, has received honoraria from Novartis, Bayer, Pfizer, Deciphera, and Roche, and has performed a consulting/advisory role for Novartis, Bayer, GSK, Pfizer, Deciphera, Roche, BMS, MSD, and AstraZeneca. **MK** has been paid by F. Hoffmann-La Roche Ltd to be an external consultant. **NS** has been paid by F. Hoffmann-La Roche Ltd to be an external consultant. **JG** has received grants/contracts from Novartis, Incyte, BMS, Pfizer, and Takeda, has received travel expenses from Amgen, Alnylam, BioMarin, Novartis, Pfizer, Roche, Servier, and UCB, and has performed a consulting/advisory role for Alnylam, Bayer, Boehringer Ingelheim, BioMarin, Daiichi Sankyo, Gilead, Janssen, Novartis, Pfizer, Roche, Servier, Sanofi, Sobi, and UCB. **DT** has performed a consulting/advisory role for F. Hoffmann-La Roche Ltd. **JW** is an employee of and has stock in F. Hoffmann-La Roche Ltd. **SF** is an employee of F. Hoffmann-La Roche Ltd. **CP** is an employee of and has stock in F. Hoffmann-La Roche Ltd. **LP** is an employee of and has stock in F. Hoffmann-La Roche Ltd. **MvM** is an employee of and has stock in F. Hoffmann-La Roche Ltd. **CLT** has received grants/contracts from MSD, has received travel expenses from MSD, BMS, and AstraZeneca, has received honoraria from and performed a consulting/advisory role for BMS, MSD, Merck Serono, Roche, Nanobiotix, GSK, Rakuten, Seattle Genetics, and AstraZeneca, and has been paid by Roche as an external consultant.