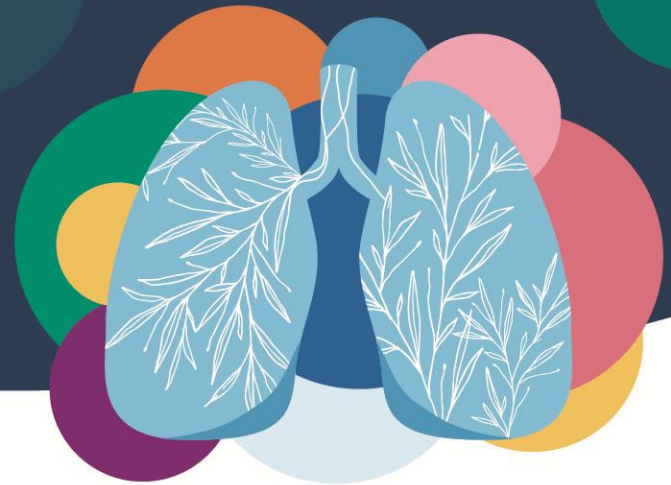
IX SIMPOSIUM ICAPEM

15 ANIVERSARIO

Asociación ICAPEM

Madrid, **28** de **octubre** de 2025

PRESENCIAL



Gender equity in clinical trial: survey on perception of patient engagement status in clinical trials.
ENGAGE: Evaluating Needs and Gaining Equality in Clinical Trials for Gender Equity

Margarita Majem

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Barcelona

BACKGROUND

- Although the number of women in clinical studies is increasing, female sex is still underrepresented (HARMONI6 10%, KN-671 30%, BRIDGE 40%, ALEX 55%, FLAURA2 60%)
- Ensuring a representative data collection is important for generalizability and reproducibility of trial data and reducing disparities in healthcare.
- Gender is an important variable in research, and knowledge should be enhanced.
- Potential factors for the underrepresentation of women:
    - include trial inclusion/exclusion criteria (concurrent diagnosis or comorbidities, contraindicated medications, pregnancy status)
    - study-related burdens (travel distance, additional expenses, and caregiver commitment)
    - lower willingness to undergo treatment or participate in the study.

BACKGROUND

- Barriers to women's enrolment in clinical trials:
  - common to all patients (limited awareness of therapeutic opportunities in trials, availability of studies for histological type, strict inclusion criteria).
  - specific factors regarding women: commitment to participate in study procedures, distrust of researchers and institutions, a lack of understanding of the importance or role of clinical research, and fear of randomization
- Role of physicians and their research inclination can also play a key role in clinical trials: lack of time to present clinical trial, no specific training in clinical trials
- Data on the gender identity of individuals who's genetically assigned sex does not align with their self-perception is not routinely collected in clinical → very little is known about the clinical participation rates of gender minorities.

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Principal Investigator and coordinator study centre: Silvia Novello, Department of Medical Oncology, University of Turin.

Aim of the study	To describe the current inclination of medical oncologists in recruiting patients into clinical trials, with a focus on gender.
Study design	Multicenter, cross-sectional/prospective, observational study conducted through an **electronic survey** Academic institutions, universities and general hospitals in different countries. Oncologists will be interviewed through a survey, assessing daily the possibility of enrolment in clinical trials for lung cancer patients.
Inclusion criteria	Eligible patients: male or female, ≳18 years, histologically confirmed NSCLC or SCLC at any stage, evaluated at decision-making visits for any intervention approach and line of treatment. **Written informed consent**
Survey structure	Patient demographic, social and clinical data, disease characteristics, details of the proposed clinical trial, and any reasons for not considering trials or for patient refusal will be requested. **For patients enrolled in clinical trials, a prospective assessment will be conducted that monitors study adherence at specific time points (1, 3 and additional 6 months, depending on follow-up).**

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Endpoints	***Primary objective:*** to describe and compare the number of patients with lung cancer who are offered a clinical trial and to assess the enrolment rate of patients by sex. ***Secondary endpoints*:** • to assess the rate accrual within prespecified subgroups defined by psycho-social background, demographic, clinical, and lung cancer characteristics • To identify the main reasons for not proposing enrolment in clinical trials; describing the rate of patient withdrawal and its correlation with prespecified subgroups; evaluating the rate of patient enrolment based on the characteristics of oncologists and clinical trials.
Statistical analysis	A descriptive analysis will be performed by calculating the patient enrolment rate and withdrawal rate. The statistically significant association between qualitative variables and outcomes will be evaluated with the $\chi 2$ test.
Sample size	Due to the descriptive nature of the study and the absence of a formal study statistical hypothesis, no sample size calculation could be performed. All patients meeting the study inclusion/exclusion criteria will be included. We hypothesize the inclusion of about 50 patients per center, but this is an exploratory assumption.
Study period	6 months from the initiation date of our study in the enrolled centres. Index date: date of the therapeutic decision-making visit in the enrolled centres

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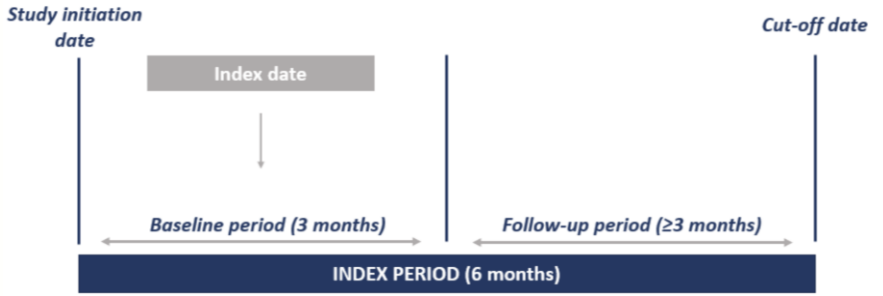

Clinical trial variables

- Details of clinical trials
  - Details of trial design
  - Availability of clinical trials for the patient (yes; no)
  - Reason for not considering clinical trials (no trial available; not eligible for inclusion criteria; no time for discuss clinical trial; patient refuse; other – if other, please specify)
  - Reason for patient refusal (negative perception of clinical trials; concern about adverse events; inability/reluctance to comply with study protocol; time taken away from work or family for frequent clinical visits; travel costs to reach the clinical trial site; other -if other, please specify)
- Details of patient adherence to clinical trial (at prespecified time points: 1, 3 and additionally 6 months from the first compilation of the survey):
  - Continue adherence to clinical study (yes; no)
  - Reason for patient withdrawal

CENTROS ESPAÑOLES INTERESADOS

Center	Principal Investigator
Hospital Universitario Lucus Augusti, Lugo	Dr. Laura Ferreira
Hospital Universitario Nuestra Señora de Candelaria, Tenerife	Dr. Ana Cardeña Gutiérrez
Hospital Arnau de Vilanova, Llíria	Dr. Nuria Piera
Hospital Universitario Infanta Leonor, Madrid	Dr. Jacobo Rogado
Hospital Universitario de Jaén, Jaén	Dr. José Antonio López López
Hospital Universitario Lozano Blesa de Zaragoza	Dr. Dolores Isla
Hospital de Sant Pau	Dr. Margarita Majem Tarruella
Hospital Universitari i Politécnico La Fe	Dr. Oscar Juan-Vidal
HG Universitario de Ciudad Real	Dr. Patricia Cruz

SITUACION ACTUAL Y PRÓXIMOS PASOS

- ABIERTO A LA PARTICIPACION DE NUEVOS CENTROS INTERESADOS EN PARTICIPAR
- EN FASE DE START-UP Y ACTIVACION DE CENTROS.
- SUBMSISSION A LOS COMITÉS DE ÉTICA DE CADA CENTRO

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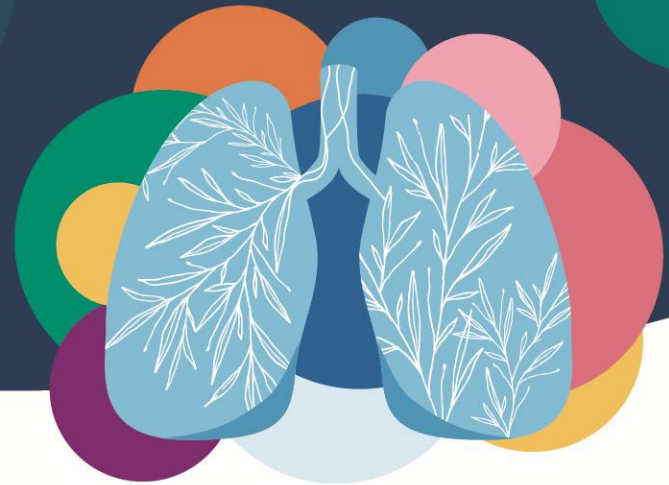

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