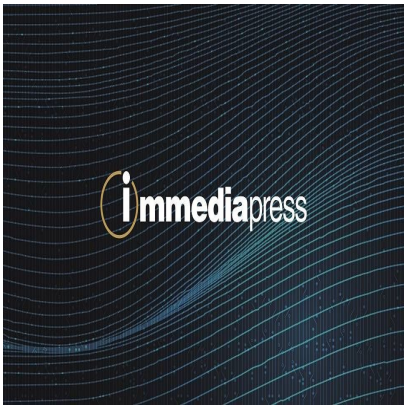


TOP-REAL investigates whether digital monitoring can support earlier detection of toxicities and preserve continuity of one of the most effective treatments for HER2-positive metastatic breast cancer

default watermark

Descrizione

COMUNICATO STAMPA â?? CONTENUTO PROMOZIONALE

BARCELONA, Spain, Nov. 20, 2026 /PRNewswire/ â?? Solti, an academic cancer clinical research group, has presented at the European ESMO AI & Digital Oncology 2026 congress the design of TOP-REAL, an international academic phase II study evaluating a proactive monitoring model for patients with advanced or metastatic HER2-positive breast cancer receiving first-line trastuzumab deruxtecan (T-DXd) plus pertuzumab.

The study incorporates digital tools to extend patient monitoring beyond hospital visits and assess whether identifying symptoms and physiological changes can support earlier evaluation and more timely management of toxicities before they worsen and compromise treatment continuity.

â??We want patients not only to benefit from advances that allow better control of their disease, but also to live better during treatment. Ultimately, TOP-REAL was conceived with a dual ambition: to improve clinical outcomes and place patientsâ?? quality of life at the center of care,â?• explained Dr. Cristina Saura, principal investigator of TOP-REAL, member of the Solti Board, Head of the Breast Cancer Unit at Vall dâ??Hebron University Hospital and Head of the Breast Cancer Group at VHIO.

Led by Solti from Spain, TOP-REAL plans to include approximately 300 patients and is already active in all three participating countries: Spain, France and Germany, with patients already on study in the first two and recruitment open in Germany. The study is conducted in collaboration with the academic groups Unicancer and WSG in France and Germany, respectively.

Making what happens between visits visible

The increasing effectiveness of treatments for HER2-positive breast cancer has made toxicity management an increasingly important part of therapeutic benefit. Adverse events can affect quality of life and, in certain circumstances, require dose modifications, treatment interruptions or discontinuation.

â??Precisely because treatments are becoming increasingly effective and allow patients to live longer, we need to pay growing attention to how they live during that time,â?• added Dr. Saura.

Among the toxicities that TOP-REAL will specifically assess is interstitial lung disease or pneumonitis associated with T-DXd. The study includes daily oxygen saturation measurements using pulse oximetry and periodic exercise tests to explore whether certain changes may support earlier medical assessment. This approach is exploratory.

A population closer to routine clinical practice

TOP-REAL will include profiles that are underrepresented in pivotal trials, such as selected patients with active brain metastases or ECOG performance status 2, with the aim of generating evidence in a population closer to routine clinical practice.

default watermark

Dr. Santiago EscrivÃ , principal investigator of TOP-REAL, Medical Oncologist at Vall dâ??Hebron University Hospital and Researcher in the Breast Cancer Group at VHIO, has discussed what additional knowledge the study may generate compared with trials that have already demonstrated the efficacy of T-DXd plus pertuzumab: â??The TOP-REAL trial is contributing to the implementation of trastuzumab deruxtecan and pertuzumab in a real-world setting, a treatment with unprecedented efficacy. It allows us to better understand how we can make this treatment available to a broader range of patient profiles and optimize the management of potential toxicities by leveraging digital tools to maintain and improve quality of life.â?•

TOP-REAL will assess treatment benefit and continuity through time to first subsequent anticancer therapy and will evaluate health-related quality of life, including changes in physical functioning through the EORTC QLQ-C30, a questionnaire used in oncology to assess different dimensions of patientsâ?? quality of life.

A European collaboration to study how to translate innovation into clinical practice

Prof. Nadia Harbeck, principal investigator of TOP-REAL and Director of the Breast Center of the Department of Obstetrics and Gynecology and the Comprehensive Cancer Center Munich at LMU University Hospital in Munich (Germany), has highlighted the international dimension of the project.

In addition to toxicity management and quality of life, TOP-REAL will explore the feasibility and safety of T-DXd rechallenge in selected patients and will include analyses of tumour biopsies and blood samples to study biomarkers related to treatment response and toxicity.

Digital and patient-centred follow-up

TOP-REAL combines a mobile application -CANKADO or Resilience, depending on the country and centre-, electronically reported patient outcomes (ePROs), pulse oximetry and smartwatch monitoring. These tools allow patients to report symptoms and physiological changes between hospital visits and

can generate recommendations or alerts, depending on the platform.

â??Identifying a toxicity early can make a major difference to a patientâ??s experience during treatment. We want to move from a model in which we wait for the patient to tell us about a problem when she comes to the clinic to one in which we can anticipate issues, support her more closely and help her manage side effects better,â?• added Dr. Saura.

Dr. InÃªs Vaz-Luis, principal investigator of TOP-REAL and medical oncologist and researcher at Gustave Roussy (Paris, France), has explained the value and novelty of the TOP REAL approach: â??TOP-REAL offers a unique opportunity to integrate innovative, patient-centred supportive care pathways into a clinical trial providing patients with access to a new and effective treatment, with the potential to further improve their care experience and outcomes. By adopting a pragmatic, flexible approach that leverages existing digital platforms and adapts to different healthcare systems, TOP-REAL will demonstrate how these pathways can be integrated into routine care across diverse settings, ensuring harmonised, high-quality supportive care for patients regardless of their healthcare setting.â?•

Sponsored by Solti, TOP-REAL is conducted in collaboration with Unicancer and West German Study Group (WSG) and is supported by AstraZeneca and Daiichi Sankyo.

default watermark

Irene AlcÃ³nirene.alcon@gruposolti.orgExternal Communications Officer

View original content to download multimedia:https://www.prnewswire.co.uk/news-releases/top-real-investigates-whether-digital-monitoring-can-support-earlier-detection-of-toxicities-and-preserve-continuity-of-one-of-the-most-effective-treatments-for-her2-positive-metastatic-breast-cancer-302946914.html

Copyright 2026 PR Newswire. All Rights Reserved.

COMUNICATO STAMPA â?? CONTENUTO PROMOZIONALE: Immediapress Ã¨ un servizio di diffusione di comunicati stampa in testo originale redatto direttamente dallâ??ente che lo emette. Lâ??Adnkronos e Immediapress non sono responsabili per i contenuti dei comunicati trasmessi

â??

immediapress/pr-newswire

Categoria

1. Comunicati

Tag

1. ImmediaPress

Data di creazione
Novembre 20, 2026
Autore
redazione

default watermark