DATECAN initiative publishes guidelines for time-to-event end point definitions in breast cancer trials

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The DATECAN initiative, Definition for the Assessment of Time-to-event Endpoints in CANcer trials, has published Guidelines for time-to-event end point definitions in breast cancer trials in a recent issue of the Annals of Oncology. Standardized definitions can help researchers to more easily compare the results of clinical trials. The guidelines developed by the DATECAN initiative can help researchers to have a more uniform usage of key endpoints in the design, conduct, and

reporting of clinical trials for patients with breast cancer.

DATECAN was initiated by statisticians and methodologists from UNICANCER under the leadership of the EORTC (European Organisation for Research and Treatment of Cancer) and with a grant from the ligue Nationale contre le cancer and the support of INCa (Institut National du Cancer). Members of the DATECAN leadership team include Prof Franck Bonnetain of the University Hospital of Besancon and the GERCOR INCa Datacenter, Dr Laurence Collette of EORTC Headquarters in Brussels, Dr Simone Mathoulin-Pelissier and Dr Carine Bellera of the Institut Bergonié in Bordeaux, Dr Sophie Gourgou of the Biometrics Unit at the Montpellier Cancer Institute, and Dr Andrew Kramar of the Cancer Care Center of Lille.

Prof Franck Bonnetain points out, "DATECAN should help us to elaborate recommendations that can then be used as guidelines by researchers participating in clinical trials. For this purpose, we are using a formal consensus process to obtain standardized consensus definitions of time-to-event end points for several cancer types: pancreas, breast, sarcoma/GIST, stomach, esophagus, head and neck, colon, rectum, kidney, bladder, and lung (Bellera CA, Pulido M, Gourgou S, et al. Eur J Cancer 2013). Our most recent publication focuses on the definition of time-to-event end points, as primary or secondary end points, used in randomized clinical trials for patients with breast cancer in non-metastatic and metastatic settings."

Dr Sophie Gourgou, corresponding author of these DATECAN guidelines for time-to-event end point definitions in breast cancer trials says, "Overall survival is often the endpoint used for cancer clinical trials , but today, end points such as disease-free survival are becoming increasingly common. One reason for this is that treatments are now more effective, especially in breast cancer, mortality is lower, and other measures of a treatment's efficacy are needed. The problem is, these

newer "time-to-event" end points are not well defined, so our ability to interpret results and make cross-trial comparisons is compromised."

Guidelines published previously by the DATECAN initiative include "Guidelines for time-to-event end point definitions in sarcomas and gastrointestinal stromal tumors (GIST) trials: results of the DATECAN initiative (Definition for the Assessment of Time-to-event Endpoints in CANcer trials)" for sarcoma (gastrointestinal stromal tumors) by Bellera et al. (Ann Onc 2015 26;(5):865-872), "Guidelines for time-to-event end-point definitions in trials for pancreatic cancer. Results of the DATECAN initiative (Definition for the Assessment of Time-to-event End-points in CANcer trials)" for pancreas by Bonnetain et al (Eur J Cancer 2014 50;(17):2983-2993), and "International Guidelines For The Definition of Time to Event Endpoints (Tee) in Renal Cell Cancer Randomised Clinical Trials: Results Of The Datecan Project" in *Annals of Oncology* by Kramar et al. (Ann Onc 2014 25;(Suppl 4): iv280-iv304, 2014).

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