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miscellanea

S22 **ERA-Net TRANSCAN JTC 2011: Critical aspects of the startup procedures of an International Academic Clinical trial (ET-FES), funded by the European Community (EC) and coordinated by an Italian Institution.**

M. Monti[1], D. Corradengo[2], O. Nanni[1], A. Piccardo[2], F. Matteucci[1], E. Brain[3], J. Cortes[4], N. Harbeck[5], R. Wuerstlein[5], A. Piris[4], D.F. Merlo[6], T. Degenhardt[5], A. Cesario[2], E. Rivitti[2], G.A. Rollandi[2], M. Iacozzi[2], E. Campazzi[7], S. Campora[8], D. Camporese[9], A. Gennari[10]

[1]*IRCCS Istituto Scientifico Romagnolo per lo Studio e la Cura dei Tumori - I.R.S.T., Meldola*
[2]*E.O. Ospedali Galliera, Genova*
[3]*Institut Curie - Ensemble Hospitalier - Hôpital René Huguenin, Saint-Cloud*
[4]*Vall d'Hebron University Hospital, Barcellona*
[5]*University of Munich, Grosshadern Hospital, Breast Center, Monaco*
[6]*IRCCS Azienda Osp. Univ. San Martino- IST, Genova*
[7]*IBSA Institut Biochimique SA, Lugano*
[8]*Covance, Milano*
[9]*Advanced Accelerator Applications, St Genis Pouilly, France*
[10]*E.O. Ospedali Galliera, Genova*

Background: The activation of international, non-profit clinical trial funded by the EC requires specific timelines according to the EU rules. This study describes all the logistic procedures, difficulties and time spent for the activation of the ET-FES TRANSCAN funded project in 4 EU countries.

Materials and methods: ET-FES study was funded by ERA-Net Transcan JTC 2011, sponsored by EO Galliera (Genoa, Italy) and is conducted in Italy, Spain, France and Germany. The primary objective is to validate the use of a new radiotracer 18F-FES PET/CT, targeting estrogen receptors, as a tool to predict endocrine responsiveness in advanced breast cancer. ET-FES was approved for funding from EU on 10/2012.

Results: The official start by the Italian Ministry of Health was set up on 06/2013 (8 mos after the expected/ foreseen date). Time to IRB approval was 1.5 mos in Italy, 2 mos in France and 3 mos in Spain and 13 mos in Germany. Time to Competent authority (CA) approval (from EC submission): Italy 11 mos, Spain 16 mos, France 5 mos, Germany 14+. Overall, no ethical objection was raised by the different ECs; some minor clinical and methodological issues were raised from the EC in Germany and Spain. Issues from the CAs were raised in all countries, except France (12 queries in Italy, 21 in Spain and 23 in Germany), on quality aspects of 18F-FES IMPD. At the sponsor level, the time to the final agreement signature with the 18F-FES manufacturing company required 13 mos. First patient in (Italy): 14 mos after EC approval and 20 mos after the official start of the ET-FES project, as set up by the Italian Ministry of Health.

Conclusions: From a regulatory aspect, taking into account that the ET-FES trial involves an experimental drug (18F-FES), without MA in EU, the approval process was timely completed at the EC level in Italy, France and Spain. Time to CA approval was different in the various countries and was timely achieved only in France: this was due to the different requirements from each local CA, indicating the absence of harmonized procedures as requested by the 2001/20/EC directive. Finally, at the Italian level, the critical issue concerns the administrative procedures to activate this type of EU projects, requiring a suboptimal time span, in order to satisfy all the legal aspects on contracts by public bodies, according to the Italian law. These timelines need to be considered when applying for EU calls where the allowed project duration is 3 years.