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ALMA MATER STUDIORUM
UNIVERSITÀ DI BOLOGNA

Dipartimento Medico chirurgico delle malattie digestive, epatiche ed endocrino-metaboliche

Medicina interna, malattie epatobiliari e immunoallergologiche UOC

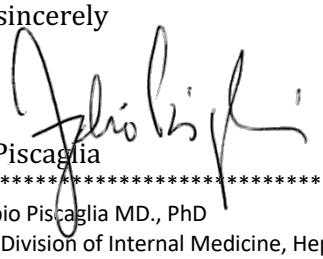
To the EMA
To all whom it may concern.

Re: 012/2007/U/Sper2007-005364-27. Dataset of Study entitled: CARATTERIZZAZIONE ECOGRAFICA DEI PICCOLI NODULI SU CIRROSI MEDIANTE CONTRASTO INFUSO PER VIA ANGIOGRAFICA SPLANCNICA

I am herewith informing about the course of the above mentioned study. The study was planned in the mid years 2000 (around 2006 then submitted to the Ethical Committee and approved in 2007). This was an expectedly much demanding study, to be conduct in the interventional angiography suite of Radiology. The study plan required dedicated personnel and dedicated equipments. Namely an ultrasound scanner of top quality for the performance of contrast enhanced ultrasound (CEUS) would be required. This would have to be moved to the angiography suite on each occasion, with the presence of an expert staff member, able to to carry out CEUS under sterile conditions (as needed in case of patients under angiography, with vascular catheters in place). At the time of the planning of the study both resources were available.
However, once the study was approved changes in our research staff members and changes in the availability of the top level scanners such resources made these conditions not available any more.

Therefore the study could not start and not even a single patient was screened.
When resources became again available (more than one year later, following training of new research staff members and possible availability of the needed ultrasound scanner) the study has lost some of its appeal due to the arrival of new imaging techniques, already published articles and new diagnostic imaging modalities (e.g. MRI with hepatocyte specific contrast agents) and new scientific challenges. As a consequence, I retained no more of sufficient interest to devote all the needed resources to this demanding study and no patient was therefore ever screened.
Accordingly there is not data set available and the study was definitively aborted.

I remain at your disposal for any further clarification.
Yours sincerely



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