The Royal Liverpool and Broadgreen University Hospitals NHS Trust

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MAP-BRA 1 – FORTIVA STUDY – CALL FOR COLLABORATORS

Dear Colleague,

Study Title: A Mesh SAfety Platform for Immediate Implant based BReAst Reconstruction (MAP-BRA) – Project 1 (FORTIVA)

Chief Investigator: Mrs Julia Henderson

Clinical Trials Unit: Liverpool Cancer Trials Unit

We are seeking expressions of interest from units experienced in implant based breast reconstruction to participate in the MAP-BRA study.

MAP-BRA is a cohort study to assess the safety of Fortiva porcine ADM in implant based breast reconstruction. This new mesh product is marketed for both sub and pre pectoral reconstruction. It is produced in a variety of sizes and is fenestrated. The aim of the study is to assess product safety with a primary outcome of implant loss at 3 months.

We would expect the material to handle in a similar way to other biological meshes, but be significantly more cost-effective.

Many new products for use in breast reconstruction are brought to market without safety data to support their use. MAP-BRA is designed with the aim of collecting safety data whilst supporting innovation and development of new techniques. This study has been developed as part of iBRAnet in support of 'no innovation without evaluation'. We hope that this protocol will act as a platform for evaluation of future mesh products.

RTI Surgical have provided an educational grant to support this study. They have had no control over the study design. They will not have access to the study data or have any influence over future publication.

A brief synopsis of the study is attached. We are seeking centres who are experienced in mesh based implant reconstruction to participate. Patients undergoing both prepectoral and subpectoral reconstructions will be eligible for recruitment. Please follow the link the complete the feasibility assessment form https://goo.gl/forms/aBo9edc5Mmd1FOjy1.

Kind regards,

Julia Henderson
Consultant Oncoplastic Breast Surgeon
Royal Liverpool Hospital
On behalf of MAP-BRA Steering Group