ISPM **Institute of Social and Preventive Medicine**
BIHAM **Berner Institut für Hausarztmedizin**
CTU **Clinical Trials Unit**

UNIVERSITÄT BERN

Seminar
on Thursday February 18th 2016, 16:00 (seminar room 1st floor)

New life for old data - an overview of the clinical trial data sharing environment

Rebecca Sudlow MSc, Global Lead Patient Level Data Sharing, Roche, UK

The last few years has seen an expansion in access to clinical trial results information from a variety of sources including the EMA and directly from pharmaceutical companies.

This presentation will provide an overview of what's available to researchers from both a clinical trial results documentation and patient level dataset perspective. It will include information on the request process that a researcher can expect to have to navigate to obtain access to patient level datasets and some hints and tips to help along the way . Roche is one of the companies who are providing access to patient level datasets via participation in the cross-company website clinicalstudydatarequest.com. The presentation will include metrics on how the website is being utilised and the types of research questions that are being submitted.

Rebecca Sudlow has worked as a medical statistician in the pharmaceutical industry for over 25 years and has contributed to drug development programs across a variety of phases and clinical indications. Since 2013, Rebecca has been closely involved in developing and delivering the tools to support Roche's Data Sharing Policy for patient level datasets. Roche worked closely with GSK and Boehringer Ingelheim to develop the cross-company patient level data request website clinicalstudydatarequest.com (launched Jan 2014). This platform now facilitates access to patient level datasets from 12 pharmaceutical companies and continues to grow. Rebecca has contributed to the EFSPI/PSI Working Group on Data Sharing and is the Chair of the PSI External Affairs Committee.

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