



Schweizerische Eidgenossenschaft  
Confédération suisse  
Confederazione Svizzera  
Confederaziun svizra

Federal Department of Home Affairs FDHA  
**Federal Office of Public Health FOPH**  
Consumer Protection Directorate

# Biomedical Research with Ionising Radiation in Switzerland



**Herca – Workshop**

26th October 2016

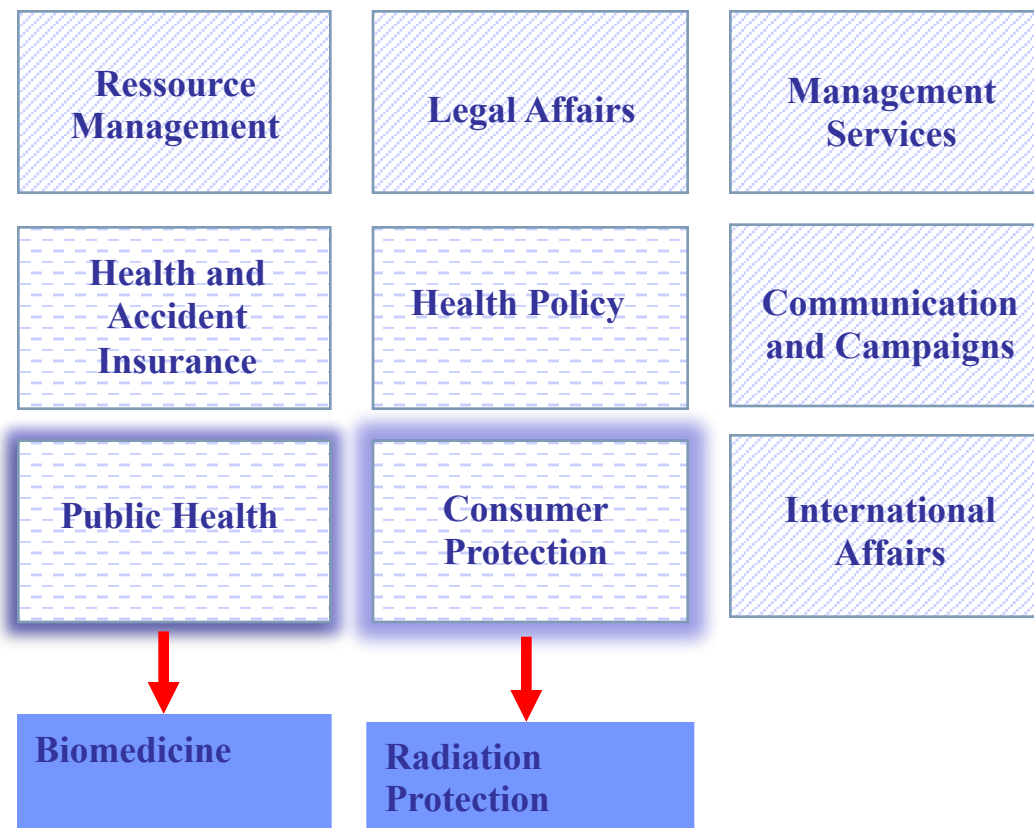
**Barbara Ott**

**Radiotherapy and Medical Diagnostics**

**Federal Office of Public Health FOPH**

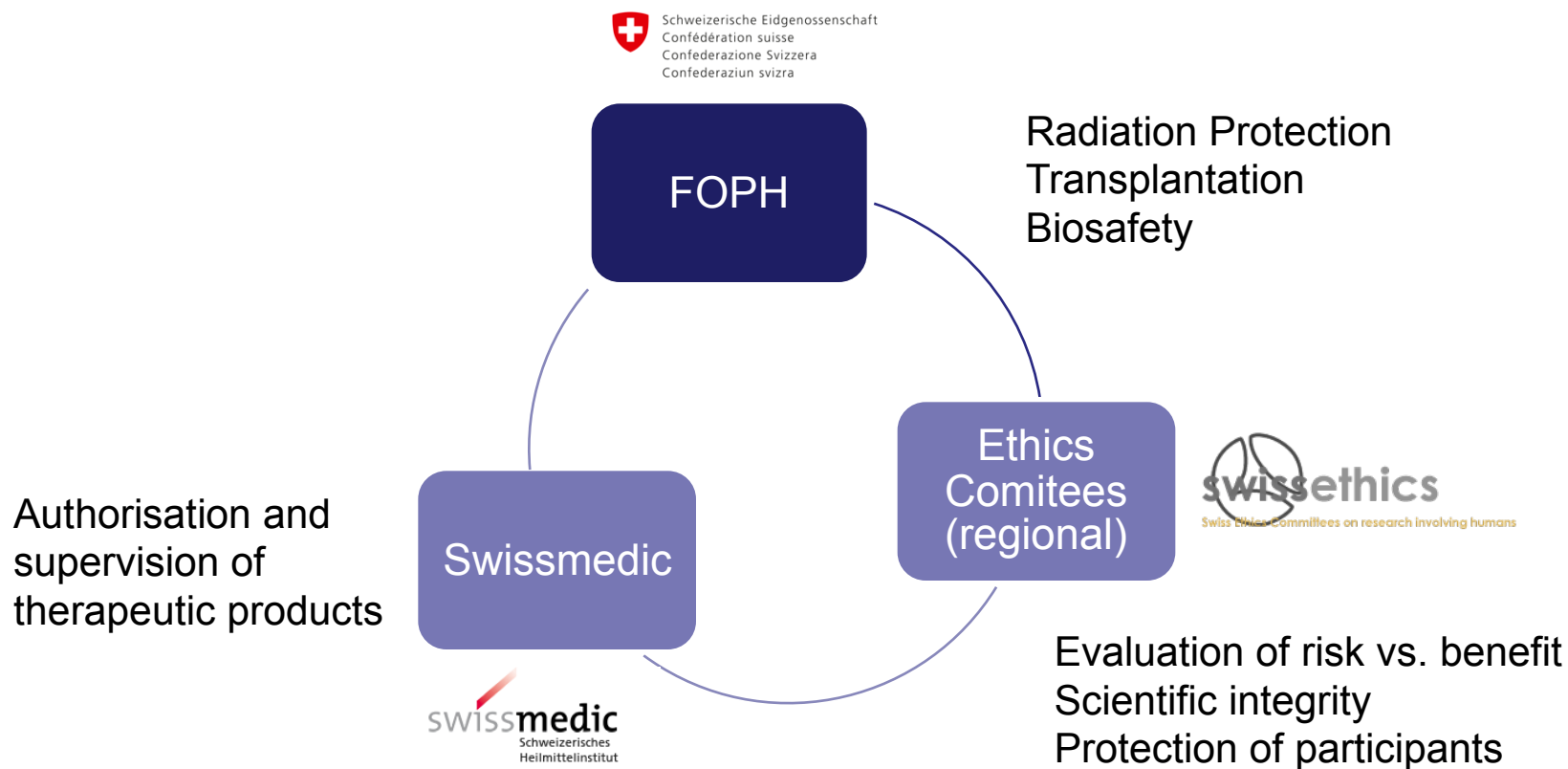


# Federal Office of Public Health - FOPH



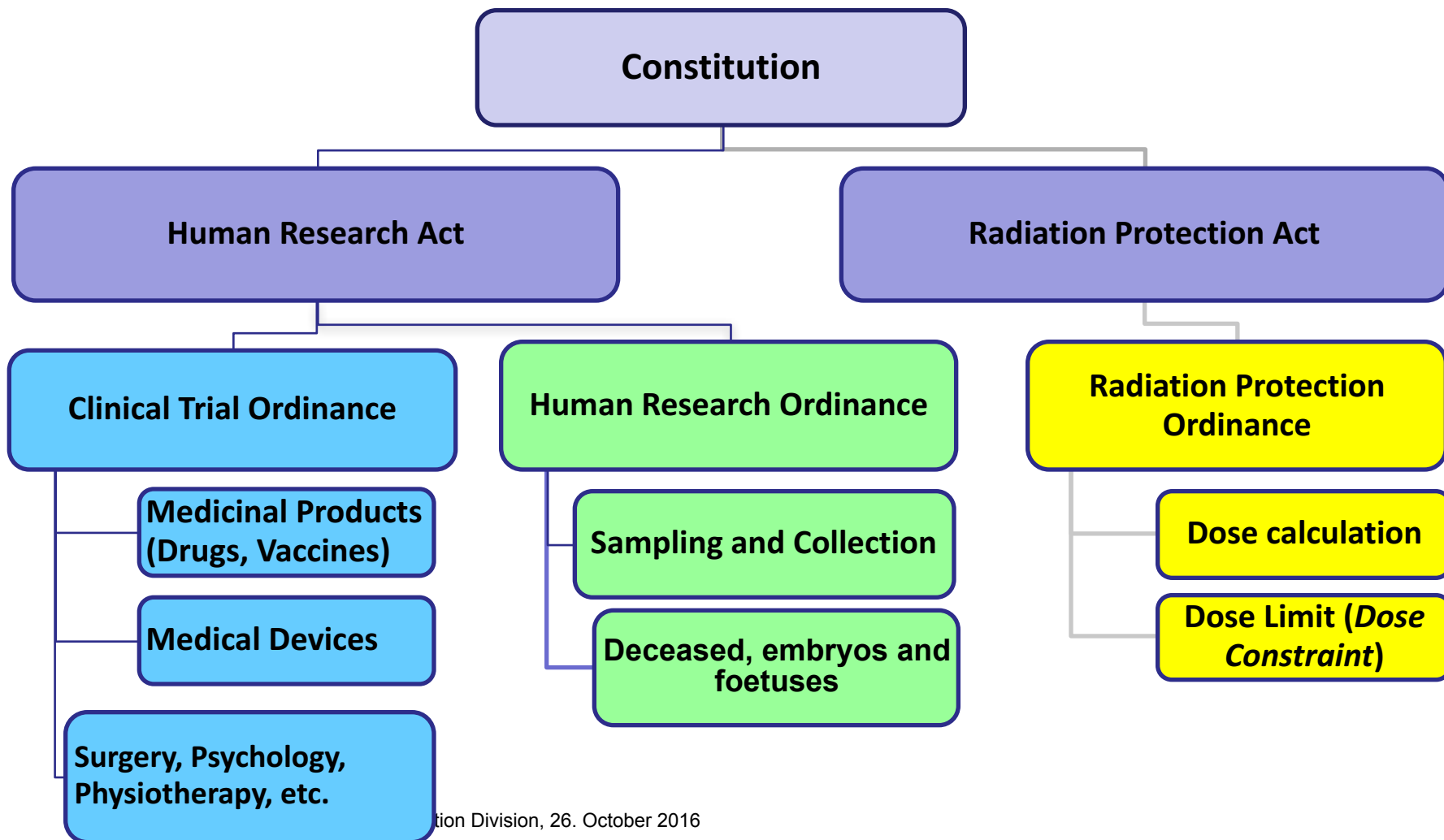


# Biomedical Research: Involved Authorities



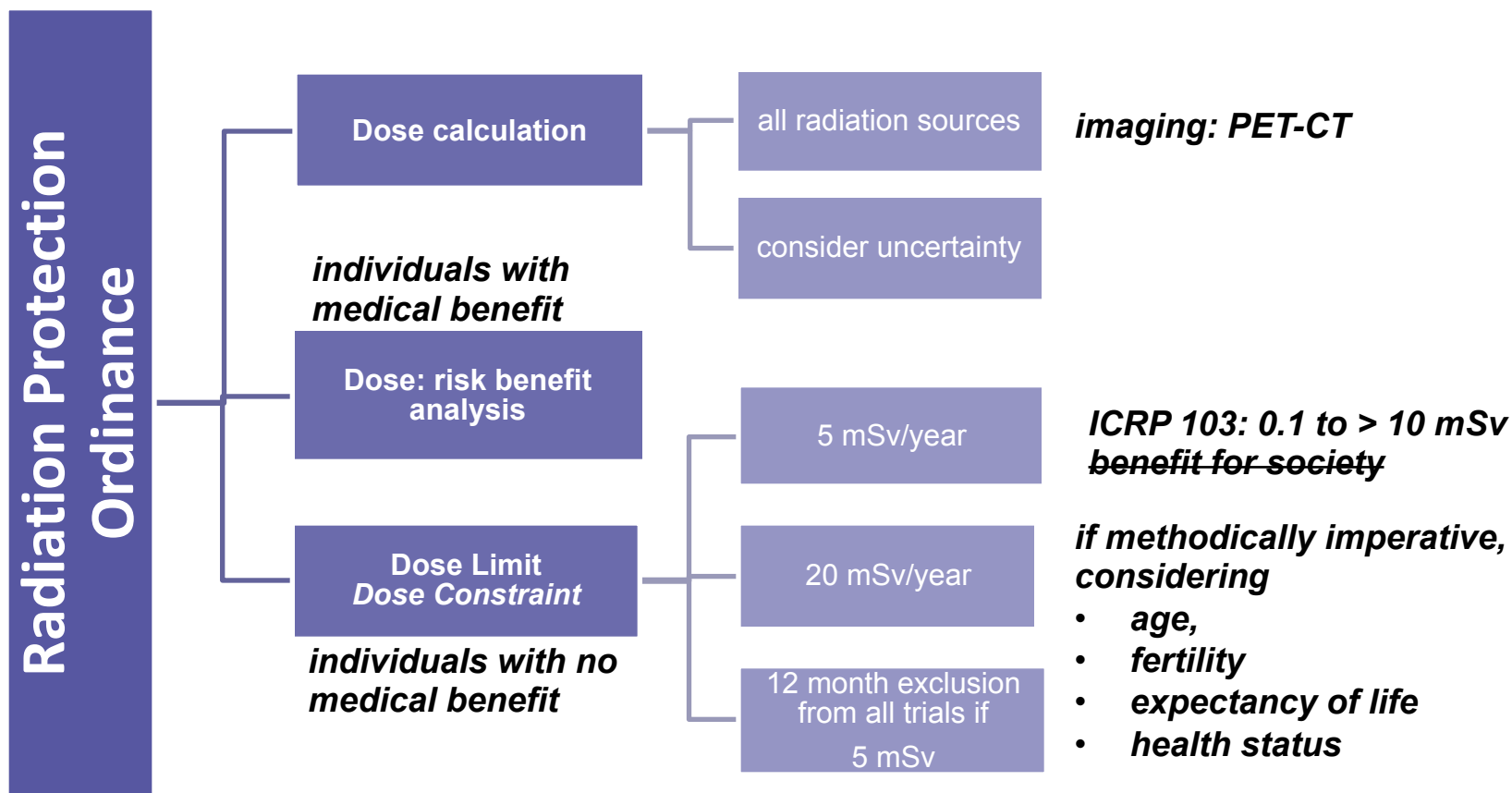


# Regulation on Biomedical Research





# Radiation Protection Regulation





## Evaluation of Radiation Protection Aspects

- Adherence to radiation protection regulation
- Verification of dose estimate
- Authorisation for the installation (for example CT) or handling radioactive substances





# Classification by Research Objective

## Clinical trials

Clinical trials including  
**investigations** with  
ionising radiation



*clinical trial on new vertebrae  
implant + fluoroscopy for  
positioning control*

Clinical trials on  
**medicinal products**  
emitting ionising  
radiation



*clinical trial on new  
radiopharmaceutical*

Clinical trials on  
**medical devices**  
emitting ionising  
radiation



*clinical trial on new  
mammography device*



# Radiation Protection Responsibilities: graded approach



## Clinical trials

### Investigations with ionising radiation

< 5 mSv or  
installation or  
approved  
radiopharmaceutical  
or routine nuclear  
medicine

> 5 mSv and not  
approved  
radiopharmaceutical  
/ non routine nuclear  
medicine

### Clinical trials on **medicinal products**

Kat A:  
approved

Kat B:  
off - label

Kat C:  
not approved

### Clinical trials on **medical devices**

Kat A:  
approved

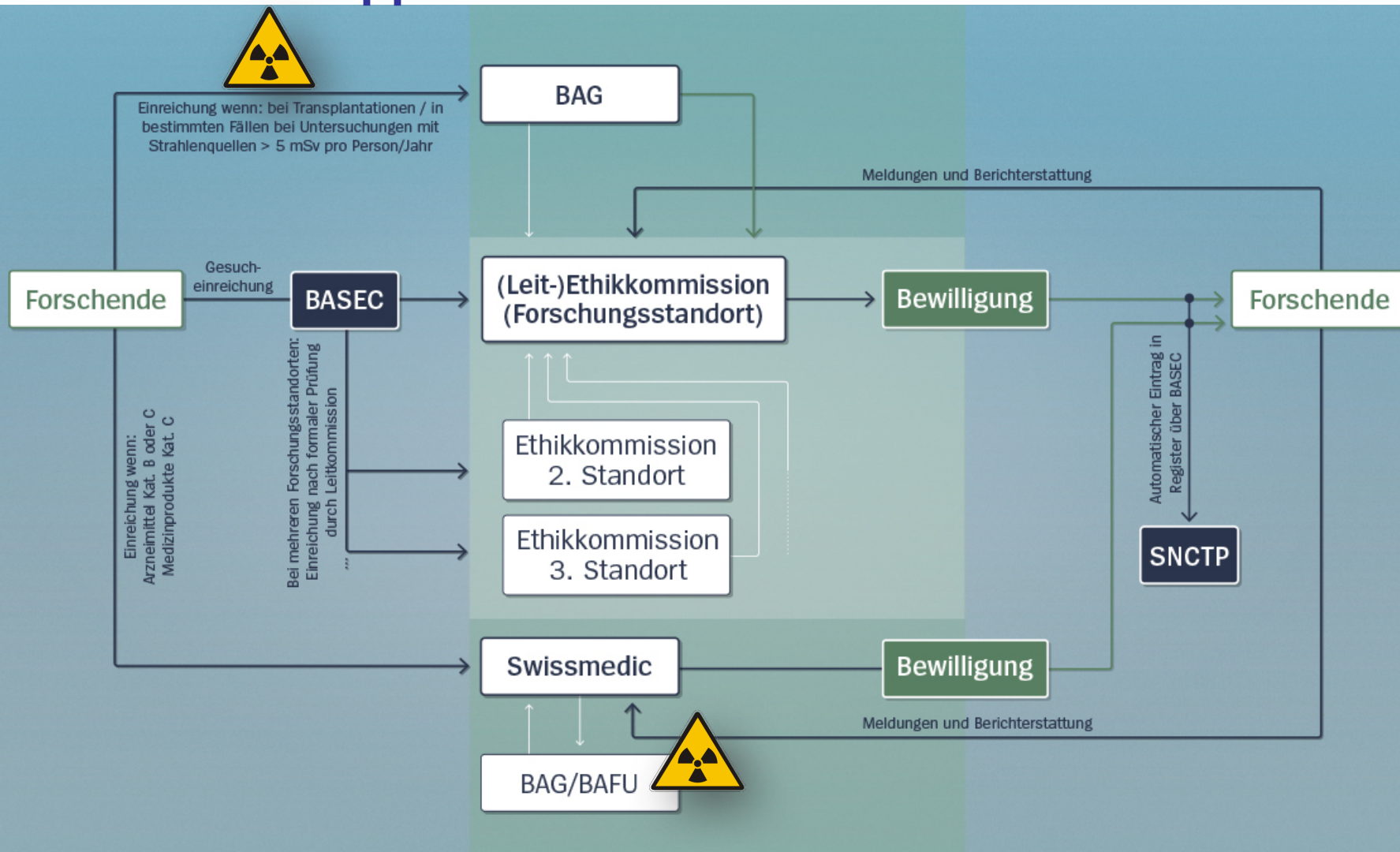
Kat C:  
not  
approved







# Clinical Trial Application





## Case: Clinical Trial with Medical Device

### Objective:

Investigate if a new 3D mammography system, (Tomosynthesis) is as good as the conventional 2D mammography system.

### Intervention 1:

Women will have a bilateral two-view mammogram (a total of four images) with the Tomosynthesis system.

### Intervention 2:

Women will have a bilateral two-view mammogram (a total of four images) with an FFDM system.

A side by side comparison of the Tomosynthesis reconstructions and the digital 2D mammographies will be performed by 6 independent radiologists.



## Case: Clinical Trial with Medical Device



- Dose estimate: verification, comparison to other mammography systems
- Compliance to dose limit? exclusion criteria
- Temporary license for the installation
- Quality assurance: acceptance test, constancy test
- Verification of dose measurements: verification
- Patient information leaflet: additional information on risk
- Information on received dose (AGD) must be handed out

***Medical justification***