# 2<sup>nd</sup> FertiTOX study meeting, 13 & 19 June 2024





### **Overview**



- Welcome
- General information
- Systematic reviews / meta-analyses
- Registry overview
- General Questions → registry
- Individual country specific information / perspectives
- Next steps: Steering committee, ....
- Next meetings
- Questions / Remarks

### Welcome



Deutsche Krebshilfe (German Cancer Aid)

- Currently we have two different email groups:
  - from REDCap users
  - from Germany (incl. additional centres, secretaries etc...)
    - → leads to doubling of e-mails

## **Sponsors**



### The support by the "Deutsche Krebshilfe" was granted!

Thank you all for your support!



# Total of 858.000,- for 2023 – 2028

Please make sure to always add the information / logos of **Swiss cancer league** and **Deutsche Krebshilfe** in presentations & publications

### **Compact version – PREtreatment forms**



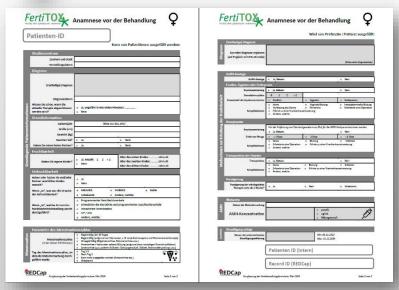


# To be downloaded from the website: Menu → Study protocol



**ICD-10** 





Interne	PrtiTO Annex → D  Trional Statistical Classification of Diseases and Related Health P				
A	Agranulocytesis (D70) Anal cercinoma (C21) Anaemia - Aplastic (D60 – D61) Anaemia - Fancari (D61.0) Angiosarcoma (C22.3)	N	Nasopharyngeal cercinoma (C11) Nebenniarenisreb: → s.Adrenocortical cercinomex Nephritar / Giomersionephrita (NGS) Nephrabiastorna → sWikms' tumourx Non-Hodgkin lymphoma (C27 – C88)		
	Biosannole + sTrophablastic diseases Brain cancer:  - Astrocychom (CT.3) - Ependymorns (CT.9) - Ependymorns (CT.9) - Gliebiasteram (CT.8) - Oligodenbroglioms (CT.8) - Medullablasteram (CT.6)	o	Ostessarcoma (C41.9) Ovary (C58):  - borderline malignancy  - sarctoma banign  - turotoma malignant  - wher		
В	- ether (C73)  Besset sousci - heigh BECA positive (215.01) - heigh BECA positive (215.01) - homene receptor positive (217.0) - homene receptor segutive (217.1) - homene receptor segutive sect howen (217) - ether (C50)  Build it implatma (C51.7)  Cervis uses cervisheam (C53)	P	Pancentic cancer (CS3): D59.2) → xTrophoblastic diseases Pleame cancer (CS3:9: D59.2) → xTrophoblastic diseases Pleamerophic undifferentiated pleamorphic sercomen Polyamentic notices (MS3) Polymycolis (MS3) Premeture control insufficiency (CS8.3)		
С	Chondrosarcoma (C41.9) Colini ulcerosa → silicerative celitiss Colon carcinoma (C49) Crohn disease (K50)	R	Prostate concer (C61)  Rectol concer (C20)  Rectoligmoid junction concer (C19)  Renal cell concinoms → «Kidney cancer»		
D	Dermatomyopitis (M33)		Rhebdomyosarcoma (C49.9) Rheumatoid arthritis (M05 – M06, M08)		
E	Endometrial carcinoma (CS4) Endometriasis (NBD) Endometriasis (NBD) Filmsarcoma (C40-C41) Filmsarcoma (C49-9)	s	Schildrüsenkrebs → xThyroid cancers Sharp syndroms → xMixed connective tissue dises Sictie ceil disease (DS7) Sigmojorzinom → xColon carcinomes		
F G	Fragile X syndrome (Q99.2) Galactosemia (£74.2)		Sjögren (Sicce) syndrome (M35) Stomach cancer (C26) Synovial sercoma (C49.9)		
	Germ cell tumour - extregonadal (ICD-0-3 M906-909)		Systemic sclerosis (including: Scleroderma) (M34)  Takayasu arteritis (Aartic arch syndrome) (M31.4)		
H	Hadgkin lymphoma (CB1) Immune thrombocytopenia (DB9)		Testicular cancer (C62):		
K	Keimzelltumor → »Germ cell tumour« Kidnay concer (C64)		nan seminamatous germ cell tumaur - teratoma     nan seminamatous germ cell tumaur - embryons carcinoma     nan seminamatous germ cell tumaur - yelk sac		
L	Laiomyopancoma NGS (ICD-O-S M8890):3) Leukseniis ilymphoid - ecute ilymphoblastic (CR1.0)  • Leukseniis ilymphoid - ehonic ilymphophos (CR1)  • Leukseniis ilymphoid - ehonic (IRS)  • Leukseniis ilymphoid - estra (CR1)  • Leukseniis ilymphoid - estra (CR2)  Liposomonom (CR3.9)  Liposomonom (CR3.9)	Т	* not seminational gerin dei cureau* yest del cercionen * stromal tumour - Leydig cell tumour * stromal tumour - Sertol cell tumour * stromal tumour - Sertol cell tumour * stromal tumour - Sertol yest Thalassenia (205) Thyriol dancer (75) Trongander (764) Trophablaste disease (201.9) Tumor syndroma (206)		
	Lung cencer (C34) Lupus erythemotosus (L93)	U	Ulcerative colitis (KS1) Undifferentiated pleomorphic sarcoma (C49)		
	Malignant fibrous histiacytoma → »Undifferentiated pleomorphic sarcoma» Malignant nerve sheath tumour (C47.9)	V	Vasculitis limited to skin (L95) Vulva carcinama (C51)		
м	Melanama (C43) Mesothelioma (C45)	W	Wegener granulomatosis (M31.3) Wilms' tumour (Kidney cancer in children) (CS4)		
	Mixed connective tissue disease (MSS.1) Morbus Crohn → «Crohn disease» Myelodypalatic syndrome (D46) Multiple aclerasis (GSS) Myelodypalatic (GSS) Myelody (GSS)	?	DISEASE NOT LISTED		



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(Vorläufige) Diagnose			Kryokonservierung	o Je, Datumo		
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			Hodengewebe			
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	Programmierter Geschied	htoverkehr	Dirwilligungserklärung		Mac 31.12.2099	
enn "la", welche Art von Un- schtbarkeitsbehandlung wurde		und programmierter Geschlechtsverkehr		Desirosa ID /Internal		
schtbarkeitsbehandlung wurde echaeführt?	Intracterine insemination     INF / ICSI			Patienten ID (intern)		

# EFORE **1**

## Our prospective registry analysis



### To be included:

- Patients with cancer or benign reasons undergoing chemotherapy and/or radiotherapy of the pelvis/testicles and/or immunotherapy
- Age: 14-50 in Austria & Switzerland, and 18-50 in Germany

### **GONADOTOXICITY**

Patient's data, fertility preservation measures

**AMH Menstruation parameters** 

> **Testosterone** Sperm parameters



> 5000



Patient's data, pregnancy outcomes, WHOQOL-BREF

AMH + FSH + LH + E2**Menstruation parameters** 

Testosterone + FSH + LH Sperm parameters

AFTER





- Keeping these goals in mind, let's have a look at the REDCap entries.
- Please keep in mind not all centres are already involved within Germany
  - → we are still awaiting ethical permission in some
- Not all patients have been added to the REDCap registry
  - → including Heidelberg

# Review of published studies



### 10 Systematic Reviews and Meta Analyses

Bone cancer

Soft tissue sarcoma

Testicular cancer

Bone marrow transplantation

Cerebral cancer

Colorectal cancer

Breast cancer

Hodgkin's lymphoma

Leukaemia

Non-Hodgkin's lymphoma

Paper published and uploaded

Paper accepted and abstract uploaded

Paper submitted and abstract uploaded

Paper submitted and abstract uploaded

Paper submitted and abstract uploaded

Abstract uploaded

Abstract summer 2024

Abstract end of 2024

Abstract end of 2024, Charité, Berlin

Abstract end of 2024, Fribourg

### **Published papers**



> JMIR Res Protoc. 2024 Mar 20:13:e51145. doi: 10.2196/51145.

Evaluation of the Gonadotoxicity of Cancer Therapies to Improve Counseling of Patients About Fertility and Fertility Preservation Measures: Protocol for a Retrospective Systematic Data Analysis and a Prospective Cohort Study

Michael von Wolff <sup>1</sup>, Ariane Germeyer <sup>2</sup>, Bettina Böttcher <sup>3</sup>, Isotta Martha Magaton <sup>1</sup>, Irene Marcu <sup>1</sup>, Janna Pape <sup>1</sup>, Nicole Sänger <sup>4</sup>, Verena Nordhoff <sup>5</sup>, Marie Roumet <sup>6</sup>, Susanna Weidlinger <sup>1</sup>

Affiliations – collapse

#### **Affiliations**

- 1 Division of Gynaecological Endocrinology and Reproductive Medicine, University Women's Hospital, Bern, Switzerland.
- Department of Gynaecological Endocrinology and Fertility Disorders, University Women's Hospital, Heidelberg, Germany.
- 3 Department of Gynaecological Endocrinology and Reproductive Medicine, Medical University of Innsbruck, Innsbruck, Austria.
- 4 Department of Gynaecological Endocrinology and Reproductive Medicine, University Women's Hospital, Bonn, Germany.
- 5 Centre of Reproductive Medicine and Andrology, Department of Clinical and Surgical Andrology, University of Münster, Münster, Germany.
- <sup>6</sup> Clinical Trial Unit, University of Bern, Bern, Switzerland.

Review > J Adolesc Young Adult Oncol. 2024 Apr 17. doi: 10.1089/jayao.2023.0185.
Online ahead of print.

### A Systematic Review of the Gonadotoxicity of Osteosarcoma and Ewing's Sarcoma Chemotherapies in Postpubertal Females and Males

Susanna Weidlinger <sup>1</sup>, Satu Graber <sup>1</sup>, Irina Bratschi <sup>1</sup>, Janna Pape <sup>1</sup>, Attila Kollár <sup>2</sup>, Tanya Karrer <sup>3</sup>, Michael von Wolff <sup>1</sup>

Affiliations - collapse

### **Affiliations**

- 1 Division of Gynecological Endocrinology and Reproductive Medicine, University Women's Hospital, Inselspital Bern, University of Bern, Bern, Switzerland.
- <sup>2</sup> Department of Medical Oncology, Inselspital Bern, University of Bern, Bern, Switzerland.
- 3 Medical Library, University Library Bern, University of Bern, Bern, Switzerland.

PMID: 38629685 DOI: 10.1089/jayao.2023.0185

# Contributing centres and those who have submitted an Ethics application



### **Switzerland: 21 centres**

 21/22 centres of the Swiss network FertiSAVE

### **Austria: 5 centres**

- Innsbruck, Uni
- Graz, Uni
- Linz, Uni: submitted
- Salzburg, Uni: submitted
- Wien, Uni & St. Anna Kinderspital

### Study is registered and Ethical votes are documented at:

→ ClinicalTrials.gov NCT05885048.

### **Germany: 28 centres**

- Berlin, Fertility centre
- **Berlin**, an der Gedächtniskirche
- Berlin, Charité
- Bonn, Uni
- **Bremen:** in preparation
- Dresden, Uni
- Erlangen: in preparation
- Freiburg, Uni
- Giessen & Marburg, Uni: in preparation
- Hamburg, amedes expertes
- Hannover, Uni
- Heidelberg, Uni
- Hildesheim, Fertility centre
- Homburg, Uni
- Karlsruhe, Klinikum
- Kiel, Uni
- Köln: submitted
- Leipzig, Uni
- Lübeck, Uni: in preparation
- Mainz, Uni
- München, TUM, Uni: in preparation
- München, LMU, Uni: submitted
- Münster, Uni
- Oldenburg, Uni
- Regensburg, Profertilita
- Tübingen, Uni
- Ulm, Uni
- Wiesbaden, TFP

## Realistic goal for 2024

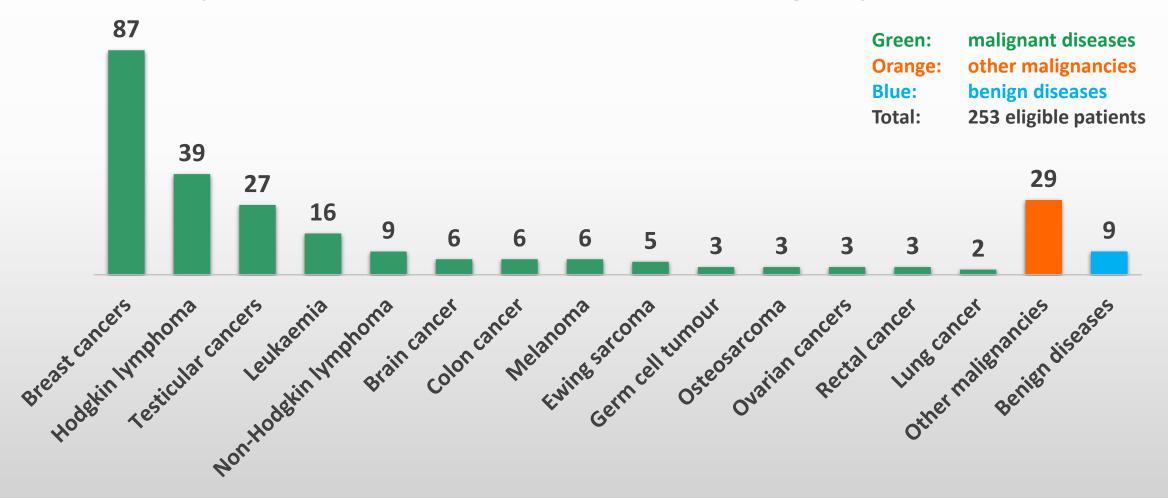


# 1000 eligible participants, recruited by 50 centres

# Analysis of the first data – total data by disease

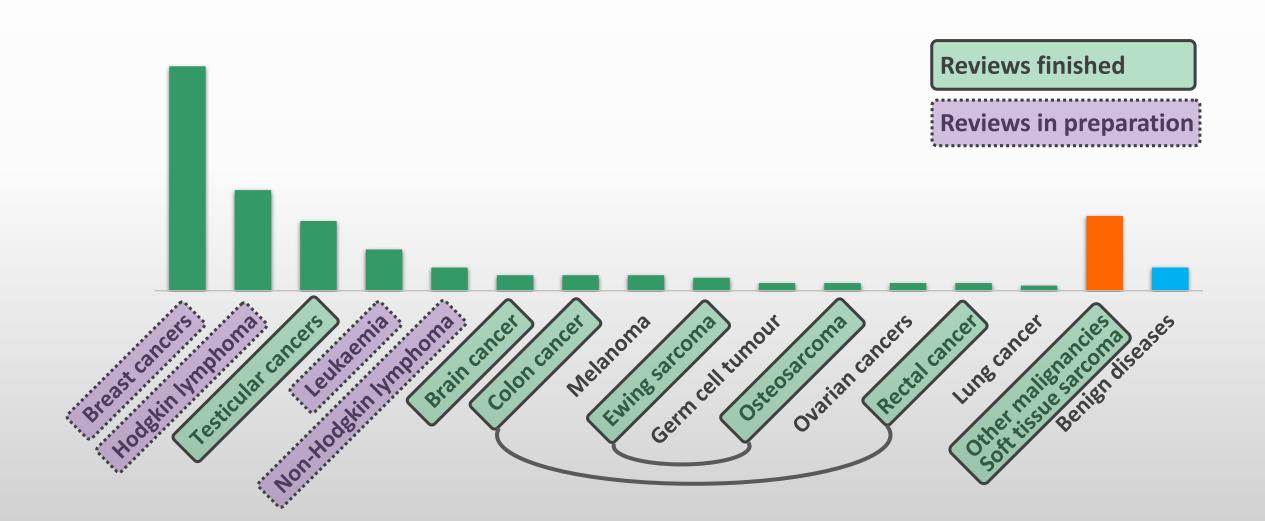


### Spectrum of diseases included in the registry so far



# Systematic reviews Meta-analyses

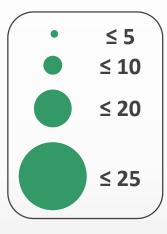




# Analysis of the first data – German centres









# Analysis of the first data – Swiss centres





# Analysis of the first data – Austrian centres





# **Germany – specific comments**



- Who does still need support with the ethical vote can write Ariane Germeyer
- The charges for the ethical votes within Germany can be reimbursed end of the year (by Ariane Germeyer), when we start getting the grant money from the "Deutsche Krebshilfe"
- Please keep in mind to always add the logo in any presentations or publication etc.
- We can support your documentation when we have the position filled with staff
- Questions

# Switzerland – specific comments



- In case the data documentation is too time consuming, you can use the paper version, uploaded on the website and send it to Irene Marcu.
- Does anybody prefer to have a specific Swiss meeting?
- Is there any chance to speed up the documentation?

## Austria – specific comments



• In case the data documentation is too time consuming, you can use the paper version, uploaded on the website and send it to Irene Marcu.

# General information regarding the documentation



• **Sperm collection** → please document the number of ejaculated provided by the patient (<u>not</u> the number of straws frozen).

• Always remember to draw a blood sample (AMH, testosterone) and note the date (menstruation date) of the time of collection.

## Next steps – Steering committee



### We need a steering committee:

- the role of the steering committee is to organise the prospective study;
- this committee will meet every 3-6 months;
- each meeting is documented by a protocol, which will be uploaded to the website (without politically information).

We suggest to include, based on the published study protocol, the following members:

- √ the coordinator
- √ the representatives of each country
- ✓ the 2 postdocs
- √ the president of FertiPROTEKT
  - → Total = 6 people. The website would be adapted accordingly.

Participation in the committee will change according to the requirements. It is not fixed forever. If it comes to data analysis etc., it might change.

## Next steps – Other meetings



### We suggest:

- Zoom registry meetings every 3 months
  - → for technical questions
- Zoom meeting with all participants every 6 months
  - → for presentation of the status quo and general discussions

### All meetings are scheduled twice in 2 different weeks:

- one around 15:00 (Wednesday)
- one around **18:00** (Thursday)

## **Next meetings**



### 1 FertiTOX registry, Autumn

**03.09.2024,** *17:00* 

**11.09.2024,** *18:00* 

### 2 FertiTOX registry, Winter

**27.11.2024,** *17:00* 

**03.12.2024,** *18:00* 

### FertiTOX → Main Assembly

**16.01.2025,** *18:00* 

**29.01.2025,** *15:00* 

## Questions, remarks?





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michael.vonwolff@insel.ch



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