

# FertiTOX Main Assembly

*16 & 29 January 2025*

**FertiTOX**  
Fertility after gonadotoxic treatments 



# Overview



- *Welcome*
- *General information*
- *Review of published studies*
- *Presentation of data (updated on 28.01.2024, includes only FertiTOX eligible patients)*
- *Documentation sheets for 1<sup>st</sup> consultation*
- *Documentation and organization of the 2<sup>nd</sup> consultation*
- *Laboratory parameters*
- *General questions*
- *Next meetings*
- *HORIZON grant*
- *Questions / Remarks*

# Contributing Centres and their Ethics Application

Study registered at [ClinicalTral.gov](https://clinicaltrials.gov) [NCT05885048](https://clinicaltrials.gov/ct2/show/study/NCT05885048)



## Switzerland: 20 centres

- 20/21 centres of the Swiss network *FertiSAVE*

## Austria: 5 centres

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

## Germany: 33 centres

- Berlin, *an der Gedächtniskirche*
- Berlin, *Charité*
- Berlin, *Fertility centre*
- Bonn, *Uni*
- Bremen: *in preparation*
- Dresden, *Uni*
- Düsseldorf, *UniKid: in preparation*
- Erlangen: *in preparation*
- Freiburg, *Uni*
- Gießen & Marburg, *Uni: in preparation*
- Hamburg, *amedes expertes*
- Hannover, *Uni*
- Heidelberg, *Uni*
- Hildesheim, *Fertility centre*
- Homburg (Saarland), *Uni*
- Karlsruhe, *Klinikum*
- Kiel, *Uni*
- Köln, *MVZ PAN-Institute: in preparation*
- Leipzig (Andro & Gyn): *Uni*
- Lübeck, *Uni: in preparation*
- Mainz, *Uni*
- Mannheim, *Uni*
- München, *LMU*
- München, *TUM, Uni: in preparation*
- Münster (Andro & Gyn), *Uni*
- Oldenburg, *Uni*
- Regensburg, *Profertilita*
- Tübingen, *Uni*
- Ulm, *Uni*
- Wiesbaden, *TFP*

# Review of Published Studies

## 10 Systematic Reviews and Meta-Analyses ([www.fertitox.com](http://www.fertitox.com)) Risk/prevalence of infertility (95% CI)

■ Bone cancer	Female 5 – 13%, Male 52 – 89%
■ Soft tissue sarcoma	Female 71%, Male 60%
■ Testicular cancer	14% (9 – 21%)
■ Cerebral cancer	20% (10 – 34%)
■ Bone marrow transplant	Female 65% (58 – 71%), Male 41% (32 – 51%)
■ Colorectal cancer	Female 27% (11 – 54%), Male 18% (13 – 26%)
■ Breast cancer	53% (41 – 64%) for AMH <0.5 ng/mL
■ Hodgkin's lymphoma	Female 21% (15 – 28%), Male 49% (36 – 62%)
■ Non-Hodgkin's lymphoma	Female 23% (14 – 35%), Male 35% (27 – 44%)
■ Leukaemia	<i>Beginning of 2025, Charité, Berlin</i>

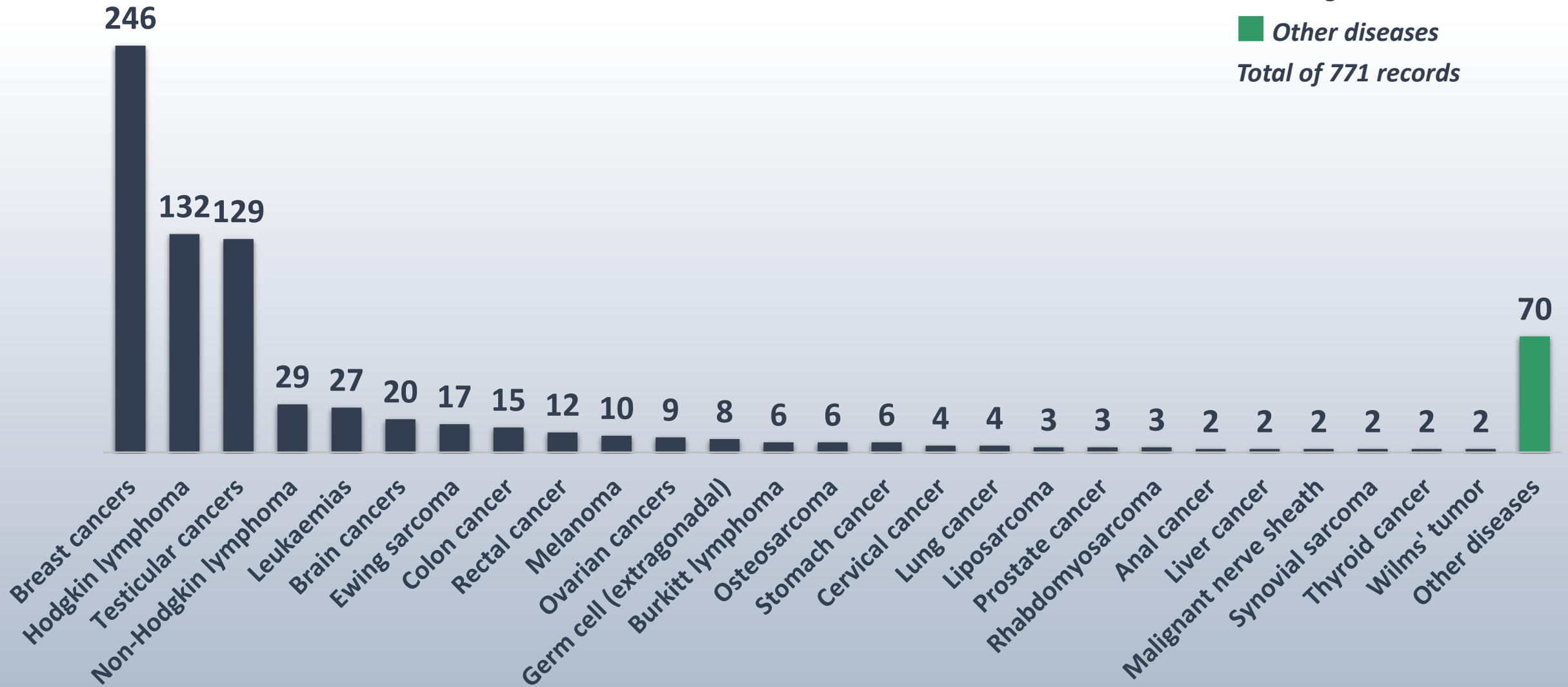
# Overall Data by Disease



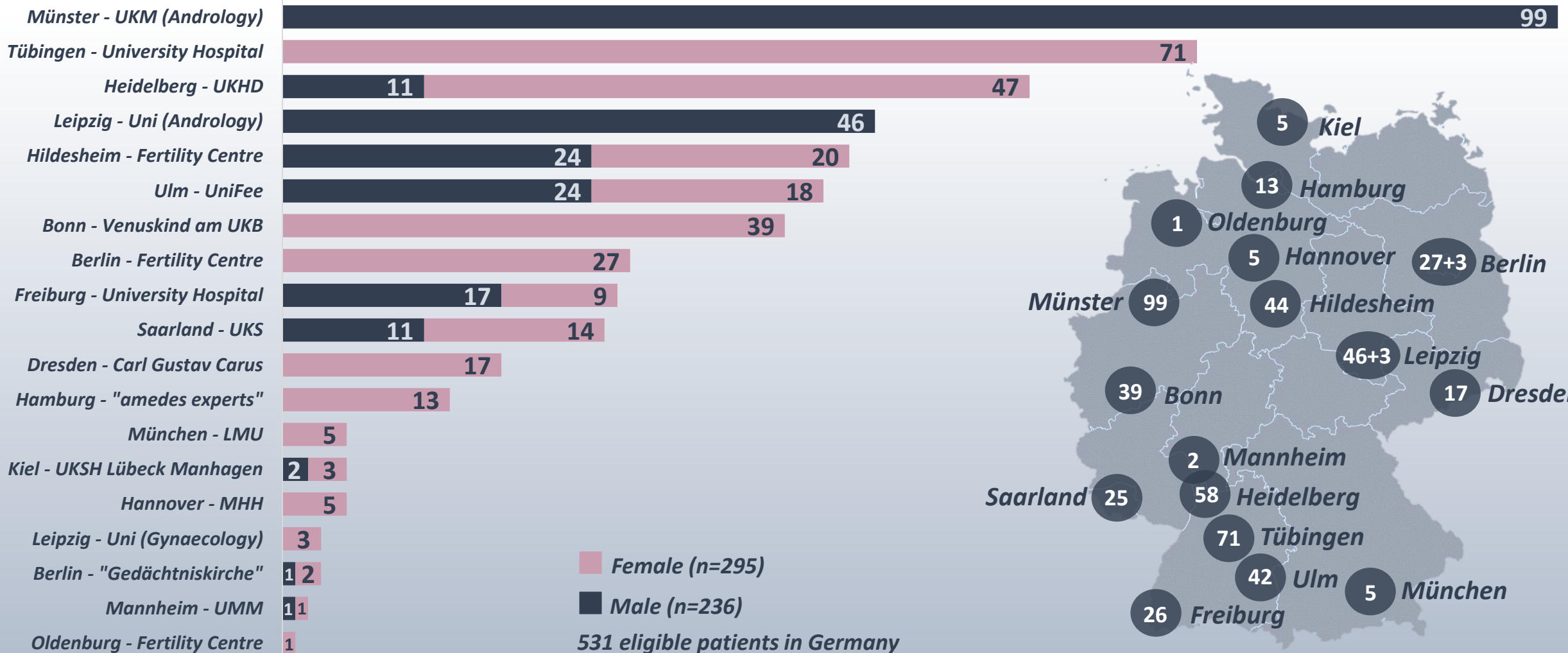
■ *Malignant disease*

■ *Other diseases*

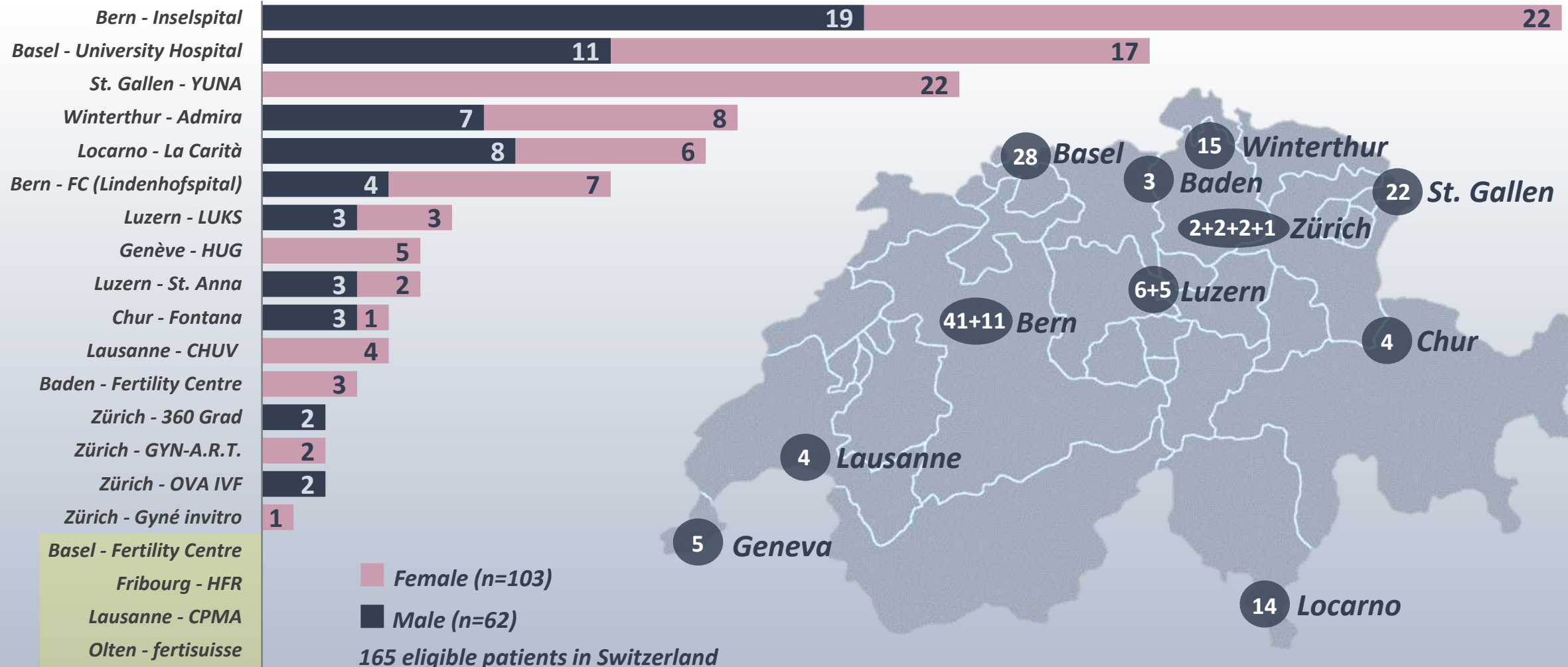
*Total of 771 records*



# Analysis of Overall Data by Sex from 19 German Centres

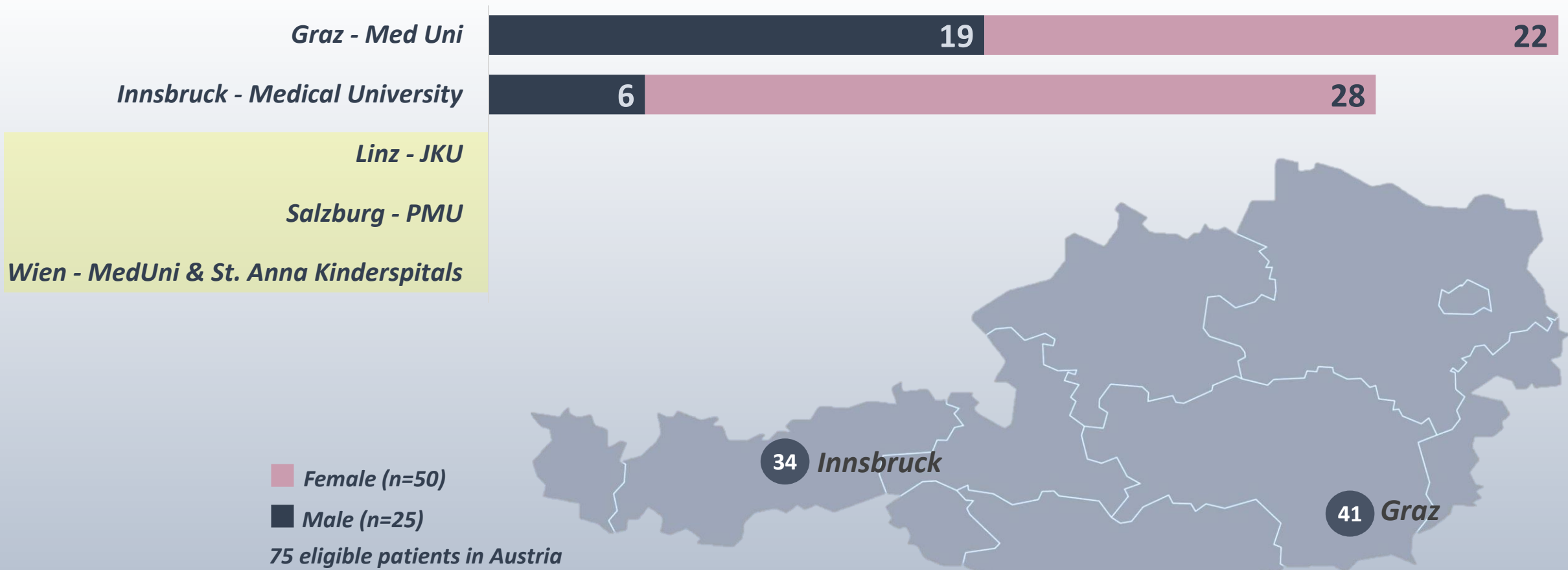


# Swiss Centres Data by Sex Plus Pending Records



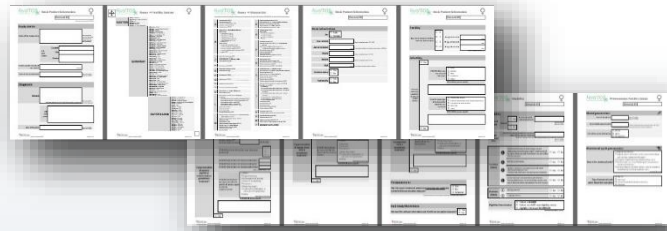


# Austrian Centres Data by Sex Plus Pending Ethics / Records

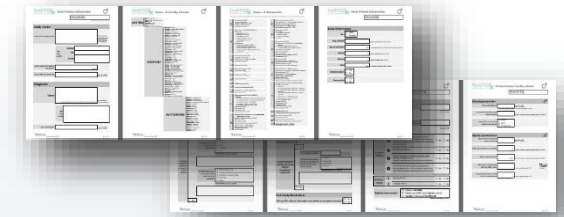




# Documentation Sheets for 1st Consultation Compact Versions – PREtreatment Forms



## ICD-10



2 pages instead of 10

These are compact versions of the medical history forms for female patients. Each form is titled 'Anamnese vor der Behandlung' and includes sections for patient ID, general information, medical history, and specific reproductive and oncological concerns. The forms are designed to be more concise than the previous 10-page versions.



2 pages instead of 8

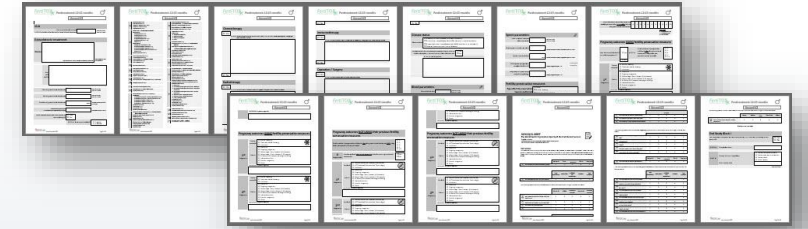
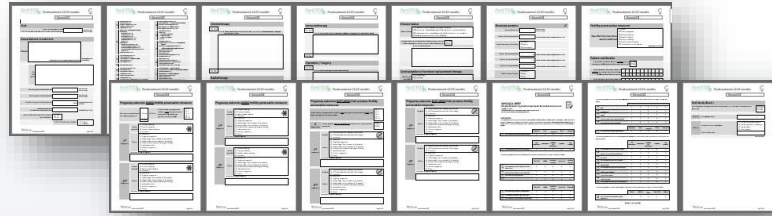
These are compact versions of the medical history forms for male patients. Each form is titled 'Anamnese vor der Behandlung' and includes sections for patient ID, general information, medical history, and specific reproductive and oncological concerns. The forms are designed to be more concise than the previous 8-page versions.

**FertiTOX Annex → Disease List**  
International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10) (MKG), Version für 2019 could expand.

<p><b>A</b></p> <p>Agonitoxicity (D70)</p> <p>Anat carcinoma (C21)</p> <p>Anemia - Aplastic (D60 - D62)</p> <p>Anemia - Fanconi (D61)</p> <p>Anoplasma (C23.3)</p> <p><b>B</b></p> <p>Bleomycin → «Trophoblastic diseases»</p> <p>Bleak cancer:</p> <ul style="list-style-type: none"> <li>• Actinomycosis (I71.9)</li> <li>• Echinocystoma (I71.9)</li> <li>• Echinocystoma (I71.9)</li> <li>• Diglanduloplasma (I71.9)</li> <li>• Metastelocystoma (I71.4)</li> <li>• other (I71)</li> </ul> <p>Breast cancer:</p> <ul style="list-style-type: none"> <li>• benign BRCA positive (Z15.01)</li> <li>• hormone receptor positive (Z15.02)</li> <li>• hormone receptor negative (Z15.03)</li> <li>• hormone receptor status not known (Z15.04)</li> <li>• other (C50)</li> </ul> <p>Burkitt lymphoma (C83.7)</p> <p><b>C</b></p> <p>Cervix uteri carcinoma (C33)</p> <p>Chondrosarcoma (C35.9)</p> <p>Colitis ulcerosa → «Inflammatory colitis»</p> <p>Colitis caecalis (C35)</p> <p>Crohn disease (K50)</p> <p><b>D</b></p> <p>Dermatomyositis (M33)</p> <p><b>E</b></p> <p>Endometrial carcinoma (C54)</p> <p>Endometriosis (N80)</p> <p>Fingert carcinoma (C40-C41)</p> <p><b>F</b></p> <p>Fibrosarcoma (C49.9)</p> <p>Fragile X syndrome (Q99.2)</p> <p><b>G</b></p> <p>Glioblastoma (C71.2)</p> <p>Germ cell tumour - embryonal (ICD-O-3 M905-909)</p> <p><b>H</b></p> <p>Hodgkin lymphoma (C81)</p> <p><b>I</b></p> <p>Immune thrombocytopenia (D69)</p> <p><b>K</b></p> <p>Karzinom → «Germ cell tumours»</p> <p>Kidney cancer (C62)</p> <p><b>L</b></p> <p>Leukämiesarcoma NOS (ICD-O-3 M8800.1)</p> <p>Leukämie:</p> <ul style="list-style-type: none"> <li>• Leukämie (lympho- / acute lymphoblastic) (C91.0)</li> <li>• Leukämie (myeloid - chronic lymphocytic) (C91.1)</li> <li>• Leukämie (myeloid - acute) (C91.2)</li> <li>• Leukämie (myeloid - chronic) (C91.3)</li> <li>• Leukämie - other (C91.4 - C91.9)</li> </ul> <p>Liposarcoma (C49.9)</p> <p>Liver cancer (C22)</p> <p>Lung cancer (C34)</p> <p>Lupus erythematosus (L93)</p> <p>Malignant fibrous histiocytoma → «Undifferentiated pleomorphic sarcoma»</p> <p>Malignant nerve sheath tumour (C47.9)</p> <p>Melanoma (C42)</p> <p>Mesothelioma (C45)</p> <p>Mixed mesodermal tumor (M85.1)</p> <p>Myeloid leukemia (C91)</p> <p>Mucosa Celsi → «Celiac disease»</p> <p>Multifocal adenocarcinoma (D46)</p> <p>Multiple sclerosis (G35)</p> <p>Myositis (M62)</p>	<p><b>N</b></p> <p>Nasopharyngeal carcinoma (C21)</p> <p>Nephradenoma → «Adrenocortical neoplasm»</p> <p>Nephritis / Glomerulonephritis (N02)</p> <p>Nephroblastoma → «Wilms' Tumors»</p> <p>Nephroblastoma (C22 - C28)</p> <p><b>O</b></p> <p>Osteosarcoma (C38.9)</p> <p>Ovary (C68)</p> <ul style="list-style-type: none"> <li>• borderline malignancy</li> <li>• serosa benign</li> <li>• serosa malignant</li> <li>• other</li> </ul> <p><b>P</b></p> <p>Pancreatic cancer (C25)</p> <p>Pleurothelioma (C39.9, C39.2) → «Trophoblastic diseases»</p> <p>Pneumothorax und/ventraler carcinoma → «Undifferentiated pleomorphic sarcoma»</p> <p>Polioarthritis nodosa (M50)</p> <p>Polychondritis (M34.0)</p> <p>Polyomyelitis (M33)</p> <p>Pneumothorax spontan (C38.3)</p> <p>Prostate cancer (C61)</p> <p><b>R</b></p> <p>Ratel cancer (C20)</p> <p>Ratelformel junction cancer (C21)</p> <p>Ratelformel cancer → «Kidney cancer»</p> <p>Rhabdomyosarcoma (C49.9)</p> <p>Rheumatoid arthritis (M05 - M06, M08)</p> <p><b>S</b></p> <p>Schilddrüsenkreuz → «Thyroid cancer»</p> <p>Sharp syndrome → «Mixed connective tissue disease»</p> <p>Skala cell disease (D57)</p> <p>Signetring carcinoma (M53)</p> <p>Strabismus (E01)</p> <p>Synovial sarcoma (C49.9)</p> <p>Syndrom (Schilddrüse/Schilddrüse) (M54)</p> <p><b>T</b></p> <p>Takayasu arteritis (M31.4)</p> <p>Testikuläre cancer (C62)</p> <ul style="list-style-type: none"> <li>• seminoma</li> <li>• non seminomatous germ cell tumour - teratoma</li> <li>• non seminomatous germ cell tumour - undifferentiated carcinoma</li> <li>• non seminomatous germ cell tumour - yolk sac carcinoma</li> <li>• embryonal</li> <li>• embryonal tumour - Leydig cell tumour</li> <li>• embryonal tumour - Sertoli cell tumour</li> <li>• other histological types</li> </ul> <p>Thrombocytopenia (D69)</p> <p>Thyroid cancer (C73)</p> <p>Trochanter (M54)</p> <p>Trophoblastic disease (D02.9)</p> <p>Tumor syndrome (D98)</p> <p><b>U</b></p> <p>Uterine cancer (C53)</p> <p>Undifferentiated pleomorphic sarcoma (C49)</p> <p><b>V</b></p> <p>Vasculitis limitat to skin (L95)</p> <p>Vöter carcinoma (C20)</p> <p><b>W</b></p> <p>Wegener granulomatosis (M31.3)</p> <p>Wilms' tumour (Kidney cancer in children) (C62)</p> <p><b>? DISEASE NOT LISTED</b></p>
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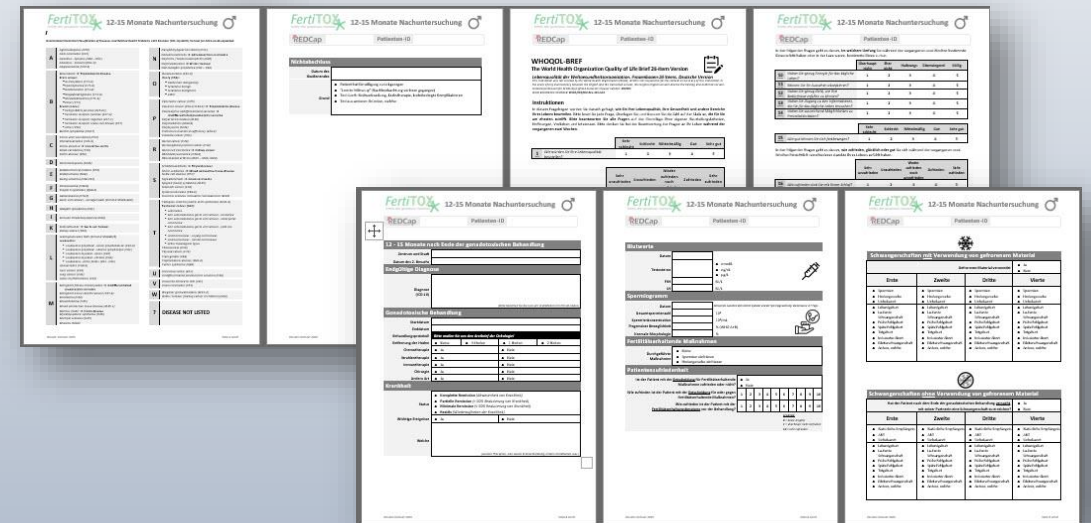
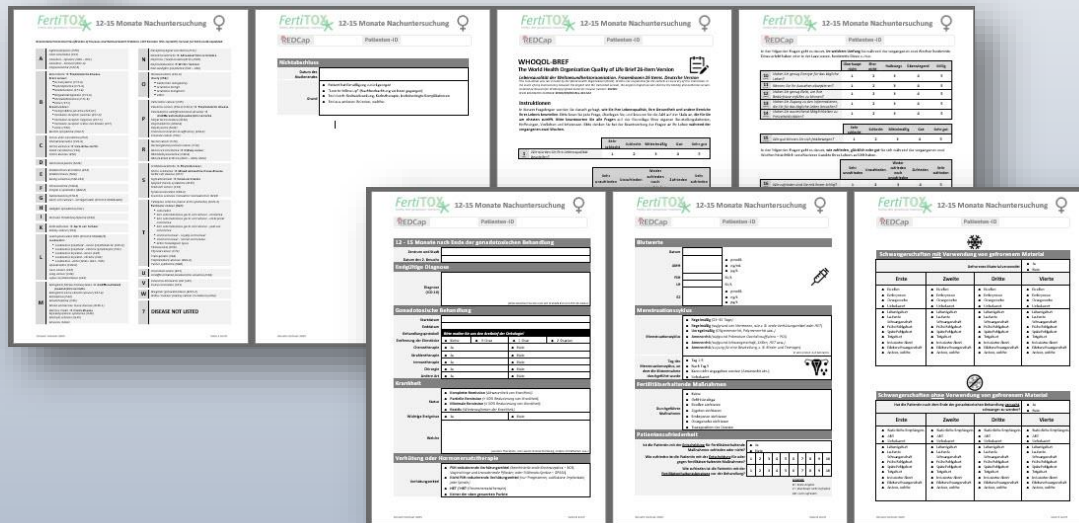
# Documentation Sheets for 2<sup>nd</sup> Consultation Compact Versions – POSTtreatment Forms



7 pages instead of 14



7 pages instead of 13



# Organization of the 2<sup>nd</sup> Consultation

## Documentation of the 2<sup>nd</sup> Consultation



Organization of the 2<sup>nd</sup> Consultation → Irene will send email reminders every 3 months

- **To centres:** a table containing records with their estimated dates and any missing data
- **From centres:** medical letter from oncologist

*Estimated date of expected end of gonadotoxic treatment*

❖ CH - St. Gallen - YUNA	12.01.2024
❖ CH - St. Gallen - YUNA	31.01.2024
❖ CH - Basel - University Hospital	01.02.2024
❖ CH - Zürich - 360 Grad	09.02.2024
❖ CH - St. Gallen - YUNA	18.02.2024
❖ CH - Locarno - La Carità	04.03.2024
❖ CH - Luzern - LUKS	07.03.2024
❖ CH - Locarno - La Carità	18.03.2024
❖ CH - Zürich - 360 Grad	31.03.2024

*Estimated date of expected end of gonadotoxic treatment*

❖ AT - Graz - Med Uni	11.03.2024
❖ AT - Graz - Med Uni	24.03.2024
❖ DE - Bonn - Venuskind am UKB	20.12.2023
❖ DE - Berlin - Fertility Centre	29.12.2023
❖ DE - Tübingen - Uni	04.01.2024
❖ DE - Münster - UKM (Andrology)	18.01.2024
❖ DE - Heidelberg - UKHD	31.01.2024
❖ DE - Berlin - Fertility Centre	02.02.2024
❖ DE - Tübingen – Uni	04.02.2024
❖ DE - Münster - UKM (Andrology)	15.02.2024
❖ DE - Heidelberg – UKHD	01.03.2024
❖ DE - Leipzig – Uni (Andrology)	11.03.2024
❖ DE - Tübingen – Uni	12.03.2024
❖ DE - Bonn - Venuskind am UKB	20.03.2024
❖ DE - Freiburg – Uni	20.03.2024
❖ DE - Bonn - Venuskind am UKB	29.03.2024
❖ DE - Heidelberg – UKHD	30.03.2024

Documentation of the 2<sup>nd</sup> Consultation → [www.fertitox.com](http://www.fertitox.com)

- Compact versions of the paper sheets with ICD-10 list and QoL
- Translations (German, French, Italian, English)

# Support for follow-up visits German centres



## Möglichkeiten der Unterstützung durch HIWI in Heidelberg

Gerne möchten wir Sie bei der Erfassung der Nachuntersuchungen 1 Jahr nach Ende der gonadotoxischen Therapie unterstützen:

- *Hierfür haben wir ein **Einladungsschreiben** für Ihre Patienten aufgesetzt (kommt im Nachgang).*
- *Die **ausgefüllten Nachsorgebögen + Arztbriefe des Onkologen** mit Information über die Art und Dauer der Therapie können Sie an [Fertitox.FRAU@med.uni-heidelberg.de](mailto:Fertitox.FRAU@med.uni-heidelberg.de) senden.*
- *Wir werden dann alle Informationen ins **REDCap** eingeben.*

# Anschreiben (Entwurf)

New Message \_ ✖ ✕

To | Cc Bcc

Subject

*Sehr geehrte Frau..., Sehr geehrter Herr ...*

*Wir hoffen sehr, dass Sie ihre schwerwiegende Erkrankung gut überstanden haben und wieder in der Lage sind ihren Alltag zu meistern und zu genießen!  
Mittlerweile sollte seit dem Ende Ihrer Therapie (Chemotherapie, Antikörpertherapie, Bestrahlung, etc.) etwa ein Jahr vergangen sein. Es ist nun wichtig, Ihre Fertilität/Funktion der Eierstöcke/Hoden zu überprüfen, um Sie bei einer eingeschränkten Funktion weiter unterstützen zu können.*



*Bitte wenden Sie sich diesbezüglich bitte an unser Sekretariat und **vereinbaren einen „Kontrolltermin Fertilitätsprotektion“ in unserer Praxis/Klinik.** Dies ist sowohl für Ihre zukünftige Familienplanung als auch Ihre langfristige Gesundheit wichtig.*

*Bitte bringen Sie zu diesem Termin den **Arztbrief des Onkologen, in dem die Art der Krebstherapie und deren Dauer erfasst ist,** mit, damit wir Sie besser beraten können.*

*Sie erreichen uns unter:*  
**Email:**  
**Tel:**

*Mit freundlichem Gruß*

← → Sans Serif ↕ **B** *I* U A ▾ ▬ ▮ ▯ ▸ ▹ ▸ ▹ “ ” 🔒 ✕

Send ▾  

# Laboratory Parameters

## PRIMARY ENDPOINTS

Females: **AMH concentration & menstruation** *before and after gonadotoxic treatment*

Males: **Sperm concentration** *before and after gonadotoxic treatment*

➤ **These parameters are absolutely essential!**

## SECONDARY ENDPOINTS

Females: **FSH & E2** *after gonadotoxic treatment*

Males: **Testosterone, FSH, sperm motility** *before and after gonadotoxic treatment*

➤ **These parameters are important, but not absolutely essential**

(Patients will not be excluded if these parameters are missing)



# General Questions

## Who pays for the parameters / reimbursement?

- *The lab values are determined as part of standard clinical care in the laboratories of the participating centres*

## (Non)-Critical missing values

- *Critical values: signed ICF, birth year, diagnosis, hormone values, units, frozen material, therapies etc.*
- *Non-critical values: BMI, smoking, partnership etc.*

## Number of ejaculate(s) ≠ ~~Multiple frozen straws~~ REDCap

Number of ejaculates (collected semen samples)



Refers to collected semen sample(s) and NOT multiple frozen straws!

1 single semen sample
2 semen samples
3 semen samples
4 semen samples
5 semen samples
>5 semen samples



# HORIZON Grant



European  
Commission

HORIZON EUROPE  
2021-2027

Improving the understanding and management of late-effects in adolescents and young adults (AYA) with cancer  
[HORIZON-MISS-2024-CANCER-01-05](#)

*“Prediction and prevention of late effects in AYA cancer survivors – An effort to understand, predict and prevent late effects in AYAs 15-39 years of age, with a focus on infertility and reproductive health PredictAYA”*

- *The coordinator is **Prof Rodriguez** from Sweden*
- *There are **18 partners**, including Heidelberg, Innsbruck and Bern*
- ***8 work packages***
- ***Total: € 7 millions***

*The work packages you could get involved with:*

- **WP4:** *Clinical research on ovarian toxicity from large cohorts across Europe*
- **WP6:** *Late effect of cancer therapies on fertility and reproduction in males*

# Next Meetings

## FertiTOX → Main Assembly

*Language: German*

*(same content for both time slots)*

- **05.06.2025, Thursday 18:00**
- **11.06.2025, Wednesday 15:00**

## FertiTOX → Swiss registry

*Same contents as Main Assembly, but held in English.*

*(same content for both time slots)*

- **05.06.2025, Thursday 16:00**
- **11.06.2025, Wednesday 18:00**

# Contact



## Switzerland

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## Germany

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[Fertitox.FRAU@med.uni-heidelberg.de](mailto:Fertitox.FRAU@med.uni-heidelberg.de)



## Austria

[bettina.boettcher@i-med.ac.at](mailto:bettina.boettcher@i-med.ac.at)

# Sponsors

**FertiTOX**  
Fertility after gonadotoxic treatments 



**krebsliga schweiz**

Swiss cancer league



**Deutsche Krebshilfe**  
HELFFEN. FORSCHEN. INFORMIEREN.

Deutsche Krebshilfe



**Caring Innovation**

IBSA Institut Biochimique SA



**Theramex**  
For Women, For Health

Theramex Switzerland GmbH

**FERRING**

PHARMACEUTICALS

Ferring Pharmaceuticals SA