

# Data Repository Project

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- **How was the project born?**
- **Aims of the project**
- **Steps**

## *How was the project born?*

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- **The Scientific Advisory Committee (SAC) review in 2010 made a number of enquiries about phase IV studies run outside the EORTC Headquarters.**
- **Two observations were made:**
  - **the Principal Investigator (PI) usually owns the data; what happens if the PI leaves?**
  - **a standard protocol template is missing.**

## *How was the project born?*

- **The SAC advice was to continue running studies outside the EORTC Headquarters, but**
  - **to create a dataset to store copies of all the data**
  - **to develop a standard template for data collection for phase IV studies**
  - **to prepare guidelines for phase IV studies**

## *Aims of the project*

**What are the aims of this project?**

## *Aims of the project*

- The aims of the Data Repository project are
  - to create a central dataset (Data Repository) for storage of all field studies data
  - to develop a standard template
  - to establish guidelines to be used to harmonize the way field studies are conducted and the way data for field studies are collected → **quality control**

**Which steps need to be done?**

- **Andrew Bottomley, Assistant Director of EORTC Quality of Life Department**
- **Galina Velikova, Chair of EORTC Quality of Life Group**
- **Colin Johnson, Chair of Module Development Committee**
- **Francesca Martinelli, Specialist in Quality of Life**

May	Phone conference
July	Meeting
August	Phone conference
September	Meeting

## *Steps*

- **First step: to create a list of phase IV studies conducted inside or outside the EORTC Headquarters.**

## Studies conducted inside the EORTC Headquarters

Module	Name	Status	PI
muscle invasive bladder	BLM30	completed phase III	Aaronson
superficial bladder	BLS24	completed phase III	Aaronson
bone metastases	BM22	validated	Chow
brain	BN20	validated	Taphoorn
breast	BR23	validated	Sprangers / Aaronson
peripheral neuropathy	CIPN20	completed phase III	Postma
chronic lymphocytic leukaemia	CLL16	completed phase III	Crofts
head & neck	H&N35	validated	Bjordal
high dose chemotherapy	HDC29	completed phase III	Velikova
lung	LC13	validated	Bergman
multiple myeloma	MY20	validated	Cocks
oesophageal	OES18	validated	Blazeby
oesophago-gastric	OG25	validated	Lagergren / Blazeby
ophthalmic	OPT30	completed phase III	Brandberg
ovarian	OV28	validated	Greimel
pancreatic	PAN26	completed phase III	Johnson
prostate	PR25	validated	Van Andel / Aaronson
gastric	STO22	validated	Blazeby
testicular	TC26	completed phase III	Holzner

## Studies conducted outside the EORTC Headquarters

Module	Name (provisional)	Status	PI
cholangiocarcinoma and gallbladder	BIL21	completed phase III	Ramage
colorectal	CR29	validated	Blazeby
cervix	CX24	validated	Greimel
elderly	ELD15	completed phase III	Johnson
endometrial	EN24	validated	Greimel
fatigue	FA13	completed phase III	Weis
carcinoid / neuroendocrine	G.I.NET21	completed phase III	Ramage
hepatocellular carcinoma	HCC18	completed phase III	Wei-Chu Chi
information	INFO25	validated	Arraras
colorectal liver metastases	LMC21	validated	Blazeby
radiation proctitis	PRT23	completed phase III	Nigel Spry / Samar Aoun ?
spiritual wellbeing	SWB33	completed phase III	Young

## *Steps*

- **Second step: to contact the PIs and inform them about the project.**

- **Third step: to define rules for data preservation and sharing.**
  - **Funding request**
  - **Data storage**
  - **Data sharing**
  - **Data transfer**
  - **Future use of Data Repository**
  - **Publication policy**
  - **Confidentiality of data**

## Rules for data preservation and sharing (draft)

- **Funding request**
  - **New proposals → section concerning data preservation and sharing strategy**
  - **Host institution and Research Ethics Committee to agree**
  - **Executive Committee to be informed**

# Rules for data preservation and sharing (draft)

- **Data storage**
  - **EORTC server, folder with restricted access**

- **Data sharing**
  - **Final locked dataset.**
  - **Reasonable time and manner**
  - **Data quality**
  - **Anonymised data**

## Rules for data preservation and sharing (draft)

- **Data transfer**
  - **E-mail, password protected compressed folder**
  - **Password should be sent in a separate e-mail**

- **Future use of Data Repository**
  - **Defined period of exclusive use of the data by the PI for primary research**
  - **After this period, new studies will be possible**
  - **Possible new studies**
    - **will need to be approved by the Executive Committee that will then inform the PI of the original research**
    - **the appropriate regulatory permissions should be obtained**
    - **the PIs will be asked whether they would be interested in contributing to the new study**

- **Publication policy**

- **The publication policy for new studies should be part of the submitted research proposal**
- **The PI wishes to contribute to the new research → co-author**
- **The PI doesn't wish to contribute to the new research → predefined acknowledgement**

## Rules for data preservation and sharing (draft)

- **Confidentiality of data**
  - **Shared data in the Data Repository are confidential and will not be released by the funders to third parties.**

- **Next steps:**
  - **to create the dataset**
  - **to develop a standard template**
  - **to prepare guidelines**

- **As a result of this project we will be able to**
  - **identify and develop generic standards in order to keep the field study process harmonized**
  - **provide guidelines and advices to the QoL community**
  - **promote good data preservation strategies**
  - **promote the sharing of data for collaborative, high-quality and ethical new research**

**Questions?**