

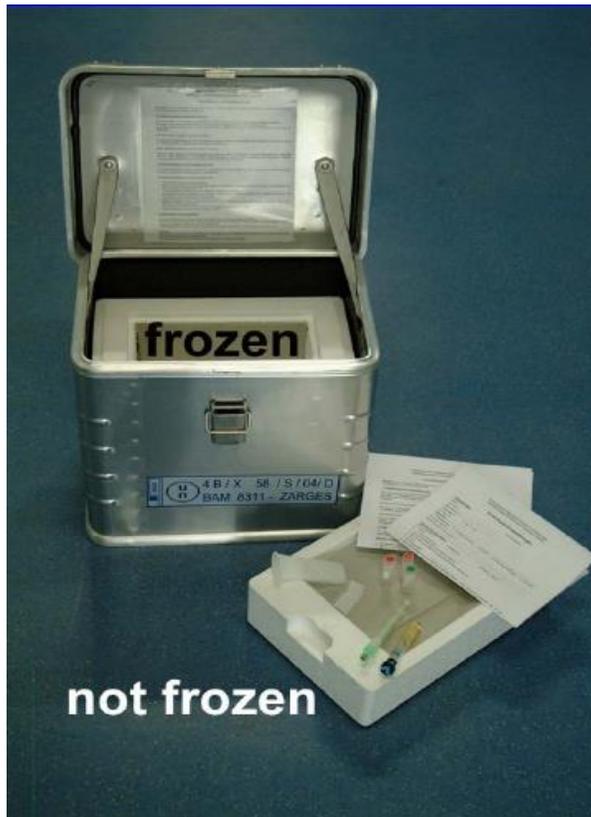


# Use of Biomaterial for Research – Impact of Data Protection

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***Chair, German Society for Pediatric Oncology and Hematology (GPOH)***

# Currently: Ideal Infrastructure for Pediatric Cancer Research in Europe

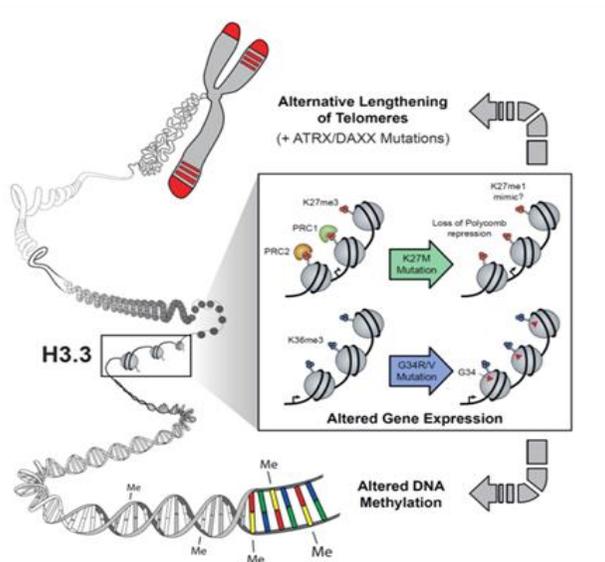


„Tumor Box“

- Basis: central, national or European biobanks for pediatric oncology
- Established logistics
- Careful consideration of data protection issues
- Urgently needed for improved diagnostics and therapies

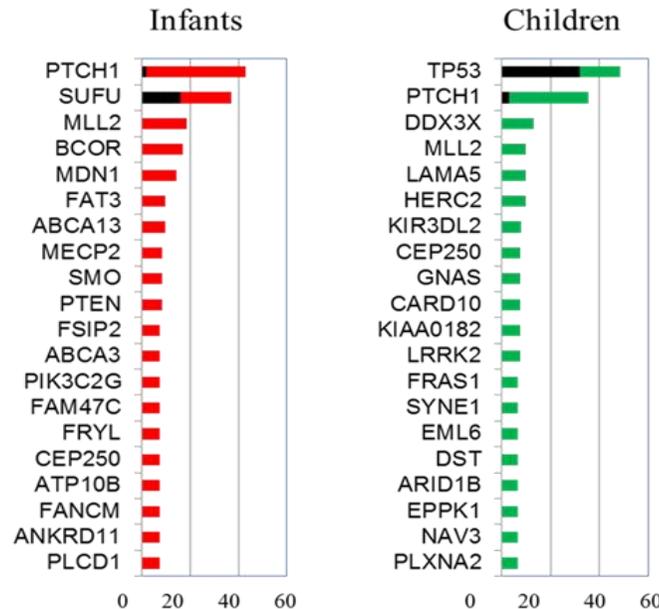
# Past: Many Innovative Therapies Identified....

## High-grade glioma



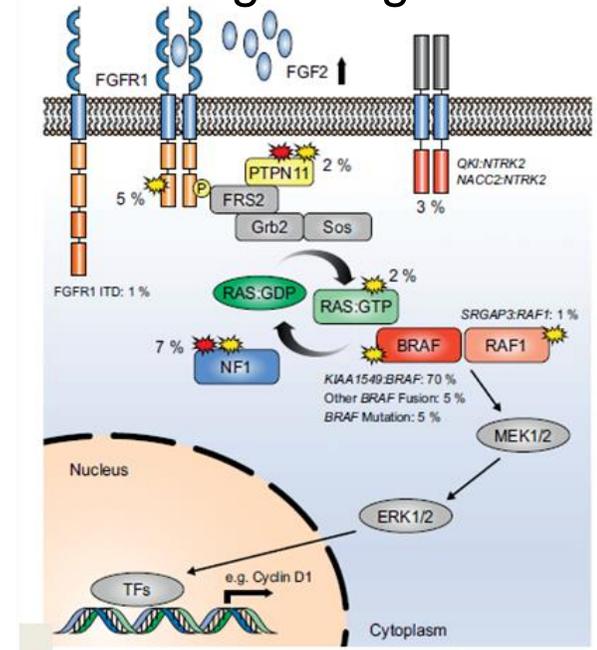
Schwartzentruber et al. Nature 2012  
 Wu et al. Nature Genetics 2012  
 Sturm et al. Cancer Cell 2012  
 Bender et al. Cancer Cell 2013  
 Fontebasso et al. Nature Genetics 2014  
 Buczkowicz et al., Nature Genetics 2014  
 Taylor et al. Nature Genetics 2014  
 Wu et al. Nature Genetics 2014

## Medulloblastoma



Rausch et al. Cell 2012  
 Jones et al. Nature 2012  
 Paugh et al. Nature 2012  
 Robinson et al. Nature 2012  
 Kool et al. Cancer Cell 2014  
 Hovestadt et al., Nature 2014  
 Northcott et al. Nature 2014

## Low-grade glioma



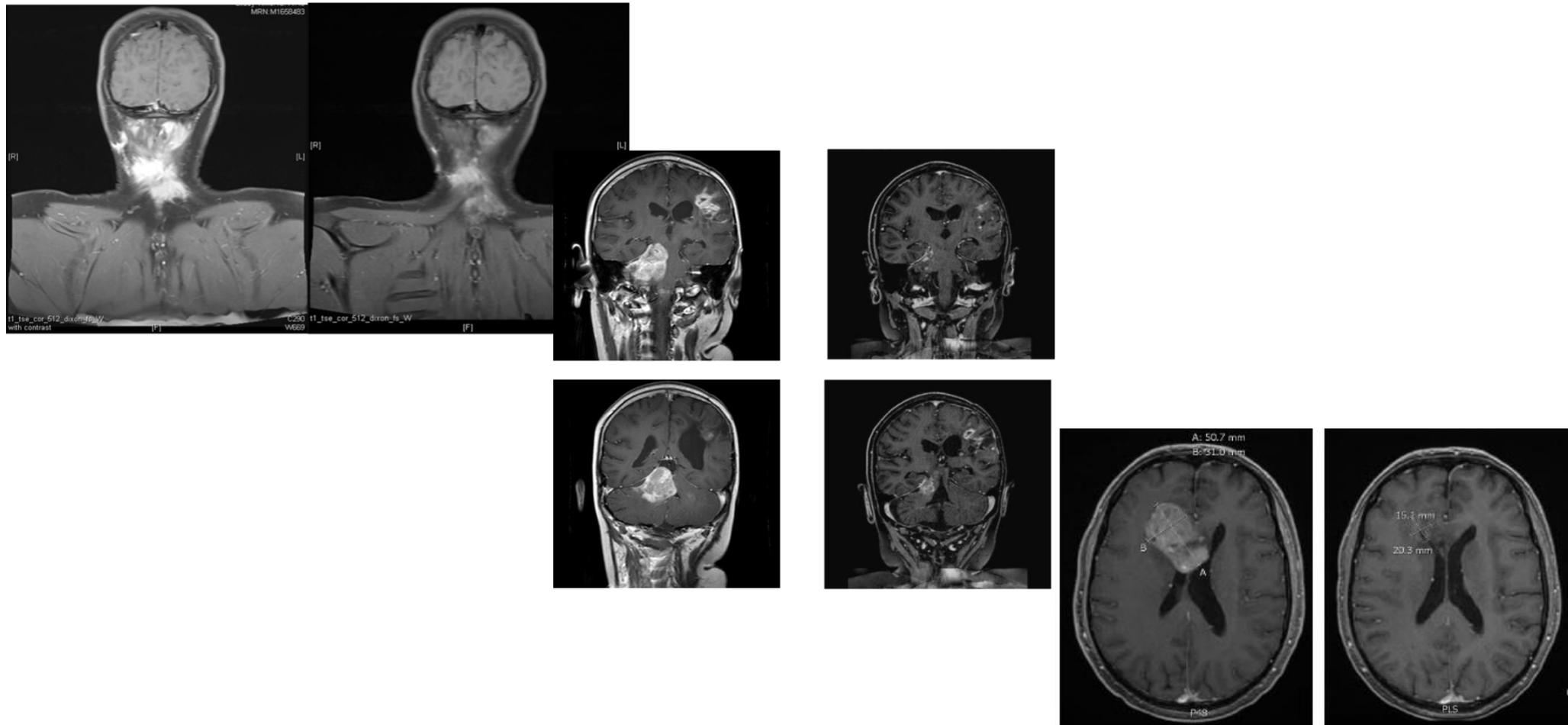
Jones et al. Nature Genetics 2013  
 Zhang et al. Nature Genetics 2013

+ Ependymoma,  
 PNET, etc.

# ...leading to encouraging clinical results:

22.11.2013

6 weeks later: 02.01.2014



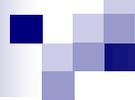
18.4.2012

2 months

13.6.2012

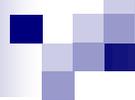
# Major Concerns: Specific and Explicit Consent

- Requirement that consent to processing data must include references to one or more pre-defined purposes **jeopardises the concept of broad consent** (= broad childhood cancer research)
- When setting up biobanks/databases, it is impossible to foresee what specific research projects the samples and data will be used for and which research partners the samples/data will be sent to
- New research approaches can arise, which would require receiving further consent – this is practically impossible
- In implementing their right to determining what happens to their information, patients should be able to give consent to open-ended use of their data and samples for childhood cancer research purposes in general



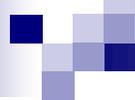
# Major Concerns: Specific and Explicit Consent

- Parent's initiatives and childhood cancer survivors see broad consent for childhood cancer research as a feasible option
- In return, access to the data/biomaterial is safeguarded by stringent procedures and the requirement for a voting procedure by an accredited ethics commission – with the goal to provide trust-building compensatory measures
- Comparatively broad consent (for childhood cancer in general) must urgently be made possible and a clear legal foundation needs to be established



# Major Concerns: Retrospective Usage of Large Databases

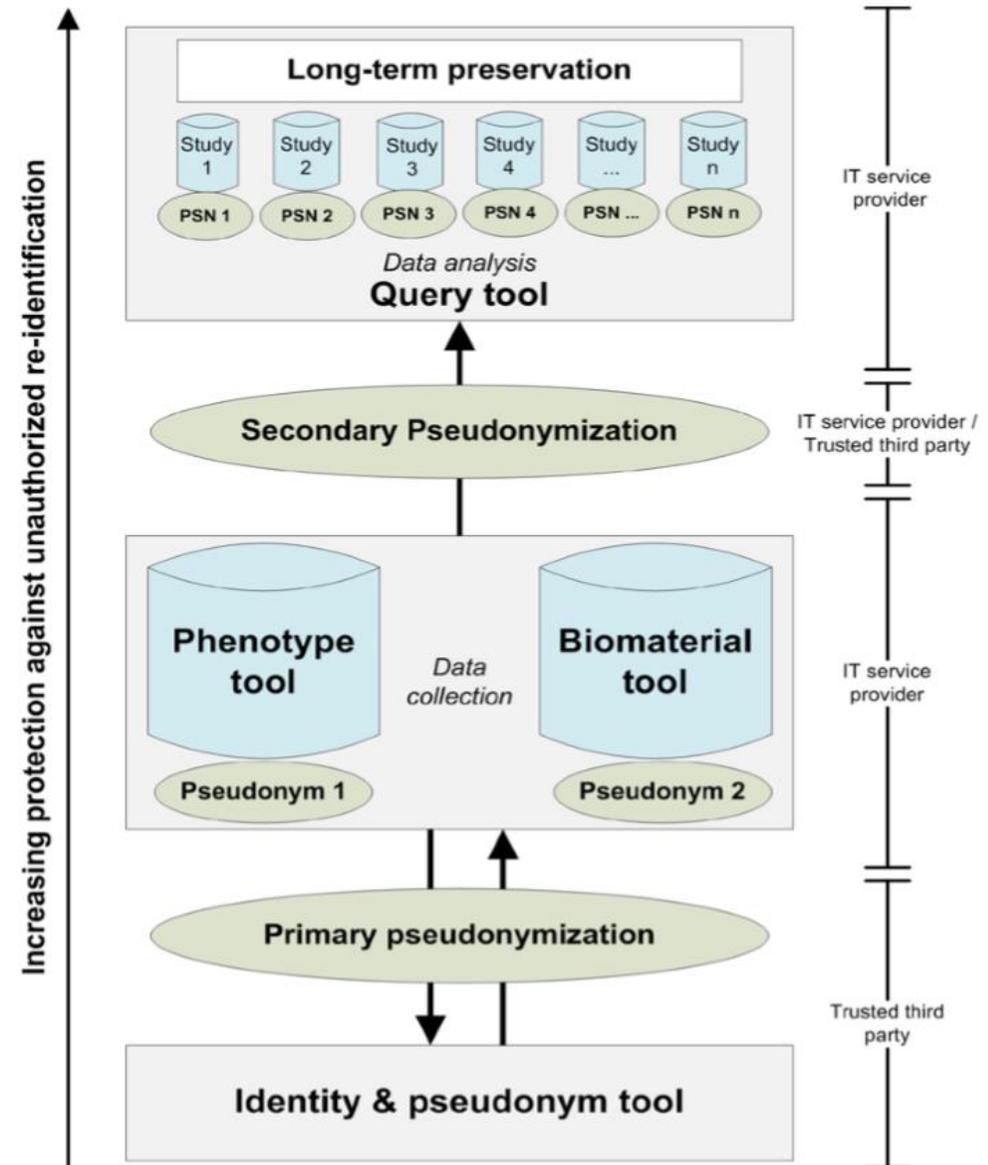
- Will largely be precluded due to the requirement to obtain explicit consent
- Important research projects would be prevented
- The requirement for exceptions (“it must be impossible to carry out the research in any other way”) is unrealistic: attempting to contact hundreds of data subjects at a later date to ask for their consent is too time consuming and practically impossible
- We urgently suggest adding “with reasonable means” in order to allow research to be implemented in another way

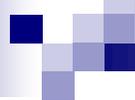


# Major Concerns: Imprecise Definition of Pseudonymised and Anonymised Data

- Pseudonymisation is a widespread tool promoting data efficiency
- Anonymisation prevents interpretation of follow-up data or feedback on important results
- Re-identifiable data can be considered anonymous to the body receiving it, if this body has no way of linking the data to its subject
- There is no clear acknowledgement of this concept in the Regulation
- It is also not clear, if rendering personal data/biomaterial anonymous can replace deleting it. This alternative is vital for research purposes so that valuable sources of information/material are not lost.

# Data protection with several levels of pseudonimisation is feasible





## Major Concerns:

# Imbalance between data subjects and data controllers

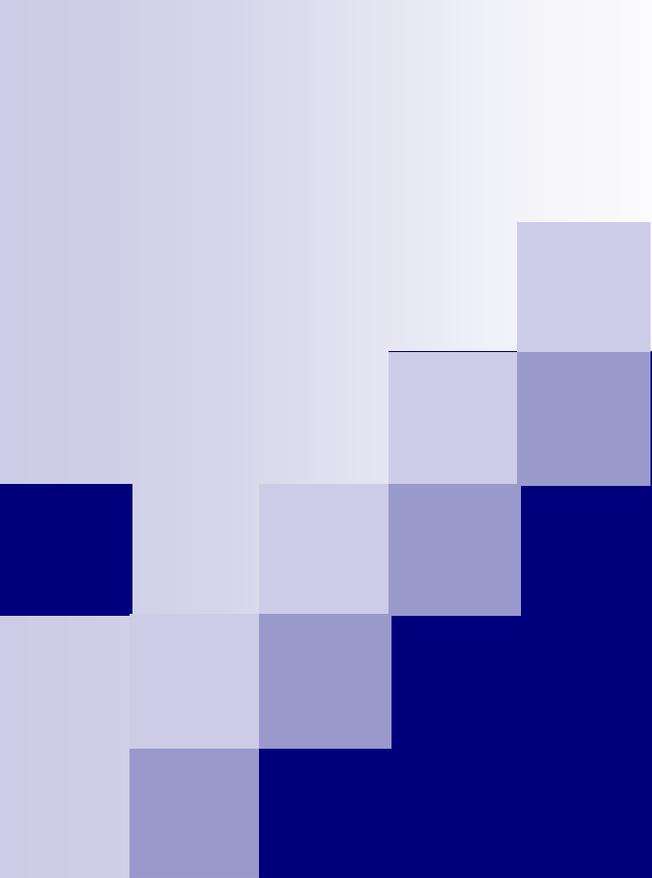
- “Consent is not a legal basis for data processing if a significant imbalance exists between the data subjects and data controllers”
- It is unclear whether this unspecific wording could be applied to the relationship between patients and the doctor treating them
- This would put the legal certainty of research projects linked to the treatment of patients at risk
- The planned amendment in the Parliamentary draft is to be welcomed

# In General:

Balancing individual data privacy and the urgent need for research progress is needed

- This means weighing up the basic rights of
- the ability of individuals to determine information passed on about themselves versus
  - the freedom of research and its benefit for society





Thank you  
for your attention  
and your support!