PALGA and the GDPR

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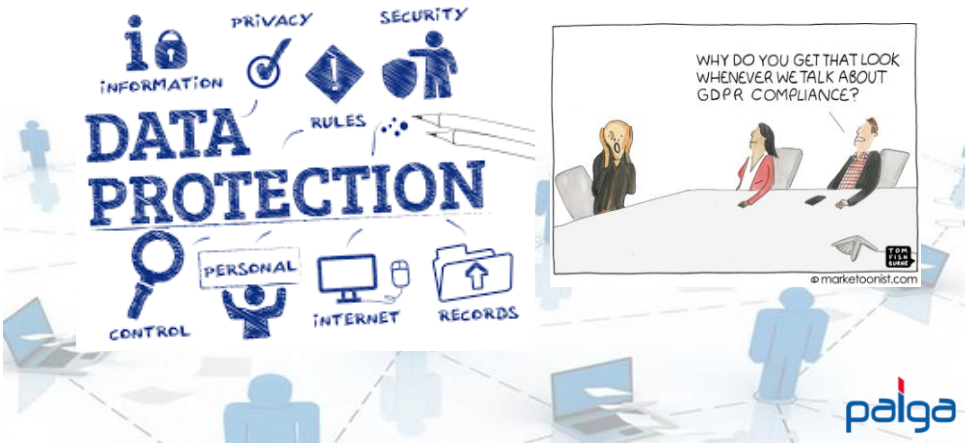
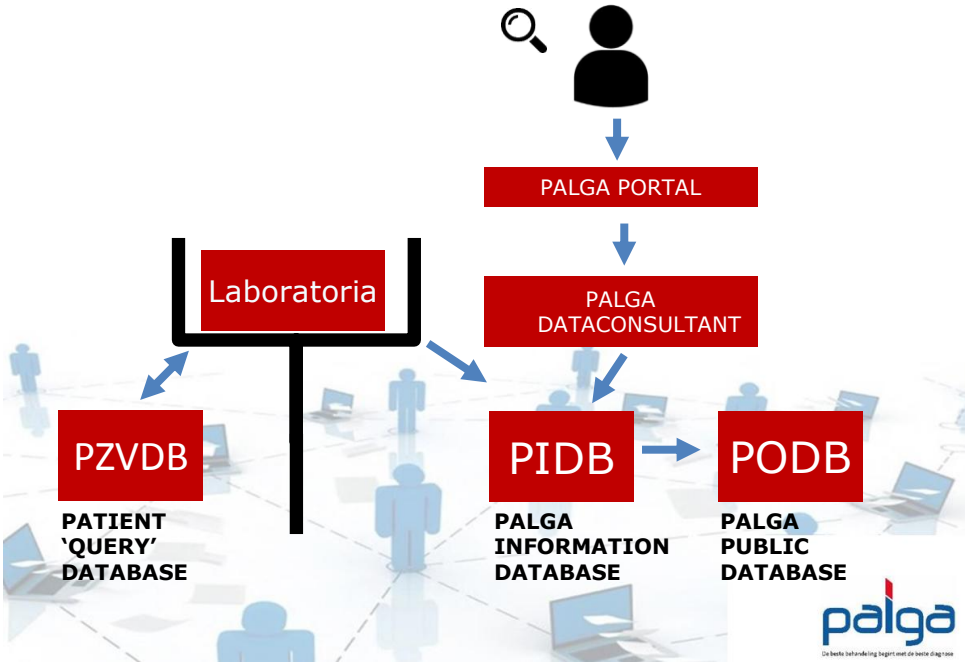
08 june 2018



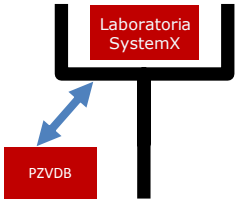
palga

palga



PZVDB (patient 'query'database)

For diagnostic care



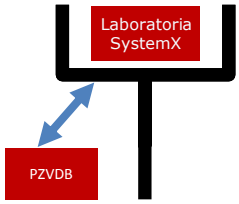
What's in it?
- Pseudonyms based on name, initial, date of birth, gender
- Pseudonyms based on social security number
- Zip code (4)
- PA-number
- Macroscopy, microscopy, conclusion

For whom?
- Pathologist, with a therapeutic relationship

When can the pathologist look into the database?
- Patients history necessary for diagnostic treatment

PZVDB is not searchable!

PZVDB

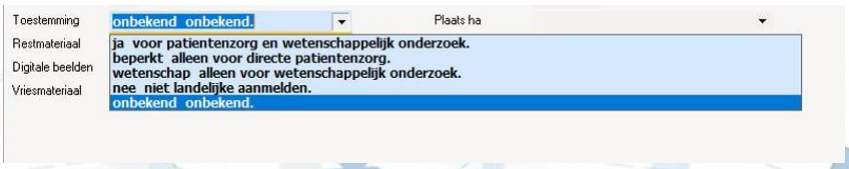


- Question: Is patient consent required?

- Data exchange essential for treatment of the patient.
- Only possible when patient record is available

- Answer: NO consent of the patient is necessary BUT

- Patient must be informed and may object

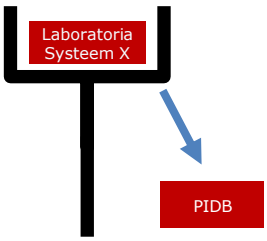


More hospitals do not allow research on data without informed consent.
Change default unknown → default NO!

No pathology data of the patient in the PZVDB and PIDB

PIDB (PALGA informatie database)

For research purpose



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For whom?

- PALGA data consultant

For the purposes of scientific research. To facilitates the fast, effective and economical use of pathology data from all Dutch pathology labs

PIDB

- Question: Is patient consent required?

- Code of Conduct for the **use of data** in Health Research and
- Code of conduct for responsible **use of material**

- Reuse of data for research purposes is compatible, although the data must be secured in the right way

- 'further use' in scientific research of **coded-anonymous** human tissue, the 'opt-out' system is acceptable

Did GDPR change the rules?

Code of conduct

- The guarantee of optimal privacy protection
- Review board available
- Patient information available
- Possibility to object
- Registration and transparency

PIDB

Data security PALGA:

- The first pseudonymising of the data in the hospital
- The Second pseudonymising at ZorgTTP
- Researcher only receives:

  date of diagnosis, gender, age at diagnosis, year, conclusion, diagnose terms,
  → (No pseudonyms, PA nrs, PA labs, zip code etc)

PIDB

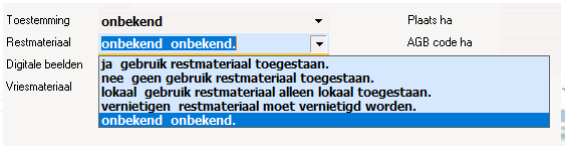
- Review of the request by a scientific/ethical board
  PALGA scientific / ethical board and Review by scientific board in the hospital

- Clear Information provide to the patient (leaflet, website etc)

- Registration and transparency → via PALGA Portal!

PIDB

- Easily accessible opportunity for objecting



- More hospitals do not allow research on materials stored in the PA labs without informed consent.

Change default unknown → default NO!

PIDB

- Data is coded-anonymous
  - Consent of the patient is not possible (No traceability to the patient) / not desirable:
  - The patient population is to big and/or it's not ethical to go back to the patient.
  - Appearance of selection bias.

- Answer: NO consent of the patient is necessary BUT

➢ Answer: Yes consent of the patient is necessary when

- Cohort studies
  - Feedback of data on patient level

In short

GDPR compliant Tool BBMRI (J. Bovenberg)

No (big) changes for PALGA regarding the GDPR.