How can we improve an optimal patient journey of patients undergoing whole-body PET imaging/immune cell imaging?

Immune-Image roundtable discussion: 8 experts with backgrounds in pharma, research, ethics, data and legislation gave their views on key questions regarding challenges and needs to guarantee or improve an optimal patient journey in research and clinical practice. Key outcomes are described below.

How is informed consent explained to the patients?

- The information should be complete, easy to understand, and reviewed by a lay person before being given to the patient, so they have the information they need to give informed consent.
- Summaries are useful, but from a legal perspective this remains a challenge as certain information is required to be included.
- To ensure patients trust and understand the information, it should be considered who is the best person (study researcher or treating clinician) to provide the information.
- Enough time should be given to the patient to review the information and ask any questions they might have.

How are research outcomes shared with patients?

- Procedures for sharing study results should be discussed upfront.
- The patient has the right to be informed about incidentally discovered findings on an individual level, the choice should be given in the informed consent.
- Expectations regarding the benefit of the treatment should be clearly managed upfront.

> “It is important to tell patients where their patient data will be stored and how.”

How are patients informed about data security?

- There is an obligation to explain data security in the informed consent procedure, including how the data will be protected as well as the right to have data deleted in case of withdrawn consent.
- Data security changes over time; What might be secure now might not be secure in a few years. In addition, data protection regulations differ per country, making standardisation and harmonisation between countries a challenge.

> “To ensure information in the informed consent is understandable for the patient, it should be reviewed by a lay person.”

How is data sharing explained to the patient?

- Patients should be informed that their data might also be of value for other research beyond the specific study covered by the informed consent. They might therefore be asked if they also consent to such secondary use of their data.
- It is important that patients know that data sharing facilitates research for the benefit of the broader patient community.
- Patients should be informed about which institution is responsible for data storage and transfer of the imaging results.

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