How to improve the informed consent (IC) process and understanding using 3D film or cartoon material

Institut Jules Bordet

**OVERVIEW:** Informed consent (IC) forms for clinical trials are often long, complex and technical in nature, which can be a barrier to patient enrolment, particularly for poorly educated and older patients. This initiative seeks to improve understanding of the IC process through 3D film or cartoon material, in order to improve access to trials for all patients.

**Objectives:** Improve understanding of the clinical trial (IC) process and simplify access to clinical trials for all people with cancer.

**Unmet needs addressed:**
- Lack of patient understanding of the clinical trial IC process
- Low access to clinical trials for older and poorly educated patients

**Key components:** Interactive and animated audio visual supports to support cancer patients’ decisions about clinical trial participation. The IREN tool (Informed on Research, Engaged for better treatments) is a decision aid to support cancer patients’ decisions about clinical trial participation, and is a collaborative project between clinical research professionals, patients and relatives.

**Challenges:**
- Ensuring that patients questions were answered, and that a full evaluation of the topic was carried out with patients and professionals
- Developing a tri-lingual tool
- Successful promotion of the initiative

**Outcomes:** The project won the Pfizer Oncology Award in 2016

**Development:** The project was set up by the Clinical Trial Conduct Unit of Jules Bordet Institute and required project coordinators, multimedia experts, video assembly, qualitative data experts, and translators

**Cost:** >€30,000

**Timeline:** The project started in 2016 and the tools have been available since 2017

**Targeted to reach:** >300 people with cancer entering clinical trials

**Area of focus:**
- Educating patients about ABC/mBC

**Target population:**
- All people with cancer entering into clinical trials

**For more information:**
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**Learnings applicable to ABC/mBC**

**Based on written submission from Institut Jules Bordet, 2021. The Hard-to-Reach ABC/mBC Communities Toolkit was developed as a collaboration between Pfizer Oncology and the ABC Global Alliance, with funding and support provided by Pfizer. ABC Global Alliance members and Pfizer colleagues were invited to submit breast cancer community-based initiatives that address specific needs of underserved patient populations with advanced/metastatic breast cancer. Initiatives were evaluated against criteria determined by a steering committee with members from both Pfizer and the ABC Global Alliance. Initiatives were selected for inclusion in the toolkit to highlight best practices in addressing the unique needs of this patient population. All organizations who submitted their initiatives for consideration have provided permission for the initiative information to be included in the toolkit and shared publicly. Pfizer and the ABC Global Alliance bear no responsibility for the contents of the toolkit.**