

Background

Treatment adherence is crucial for outcome improvement. Still up to 50% of patients interrupt e.g. endocrine treatment or other effective treatment choices due to side effects or miscommunication. Reasons may included limited time spent for patient information in daily routine and the intrinsic barriers to frankly tell the truth to the attending physicians. Therefore, a patient initiated survey has been compiled to comprehensively address all clinical, diagnostic and critical aspects of importance for patients by decentral data capture from patients at home via smart devices in a pseudonymized & interactive fashion to refocus on challenges regarding patients need, fears and wishes to support evidence based statistical analysis of Real World Data.

Conclusions

Despite complexity and lengthiness > 85% of patients did complete the survey. There is an apparent need to have more time for initial confrontation with diagnosis and treatment options. Patients are frequently not informed about alternative treatment options as well as patient rights. Patients frequently feel under pressure in their life threatening situation and suffer substantial lack of information as well as appropriate personal communication. Patient centricity should focus on elaborated communication and information systems that support treatment decision acceptance and adherence. Further details analysis will become available in upcoming subanalysis of the Breast BRIDGister platform survey.

Timeline

10/2019	Initial Idea & Study concept at patient congress
01/2020	Database Set Up & Proof of concept survey
2020/21	Content Set Up BY PATIENTS across groups
12/2022	Finalization of structure & positive ethical vote
01/2022	Start of Run In Phase & Preview Interim Analysis

Figures & Tables

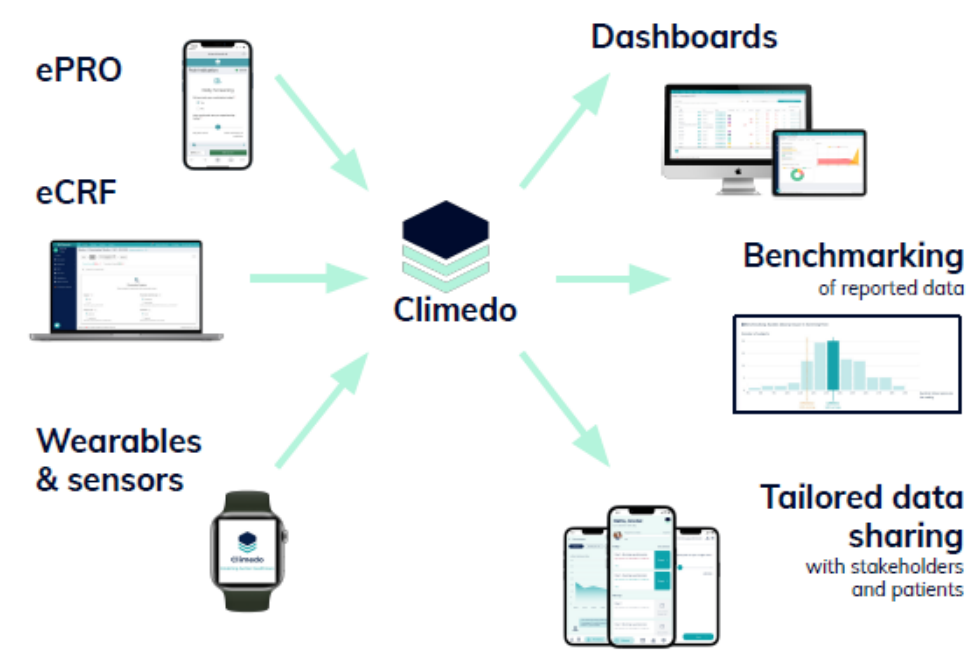


Fig. 1: Cloud based IT Plattform for easy, secure data capture without App Installation and decentral data entry via smart device from home

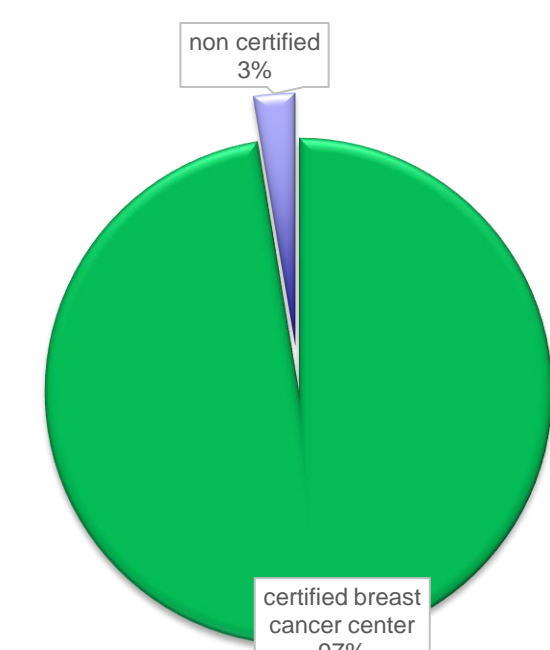


Fig. 2: Certification status of treatment site

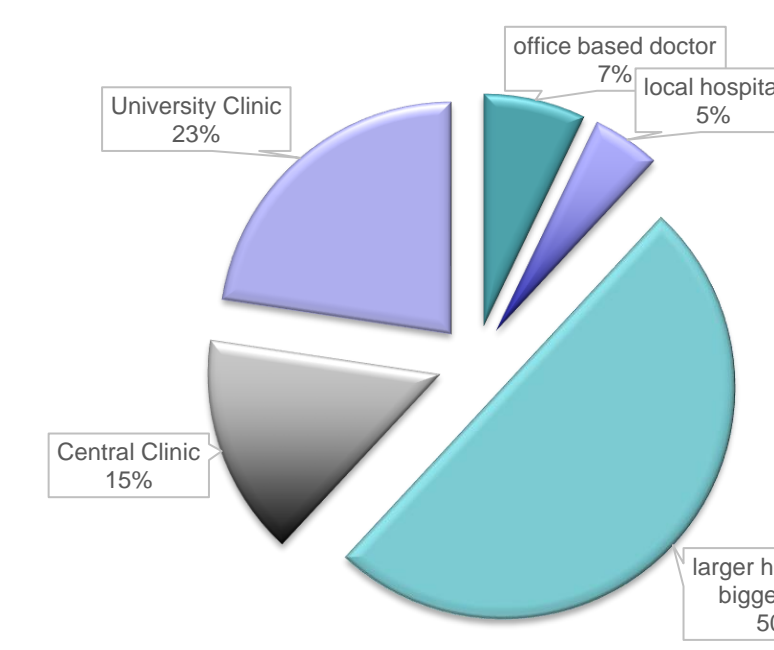


Fig. 3: Type of main treatment site

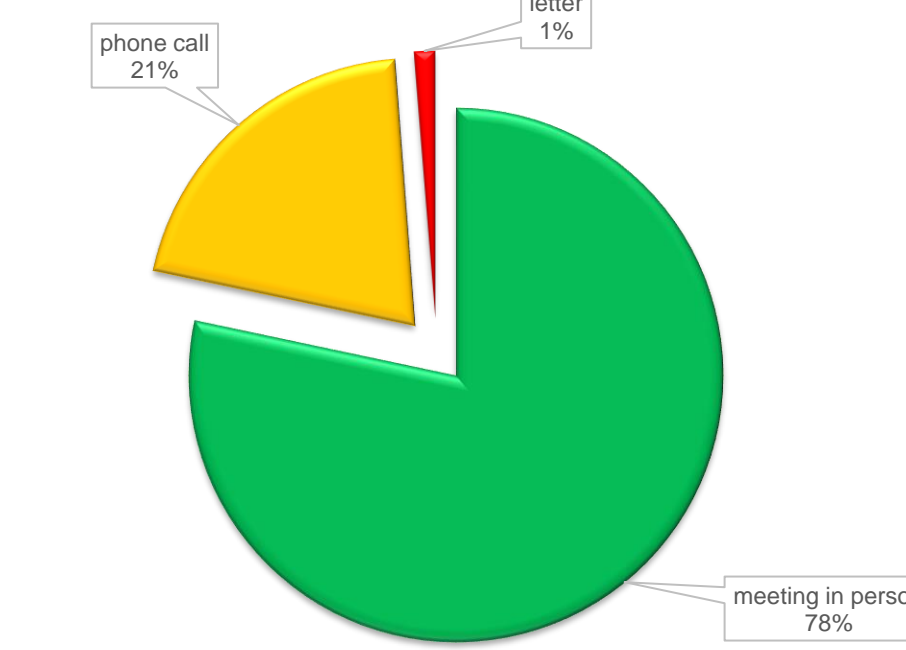


Fig. 4: Type of communicating initial diagnosis to patients

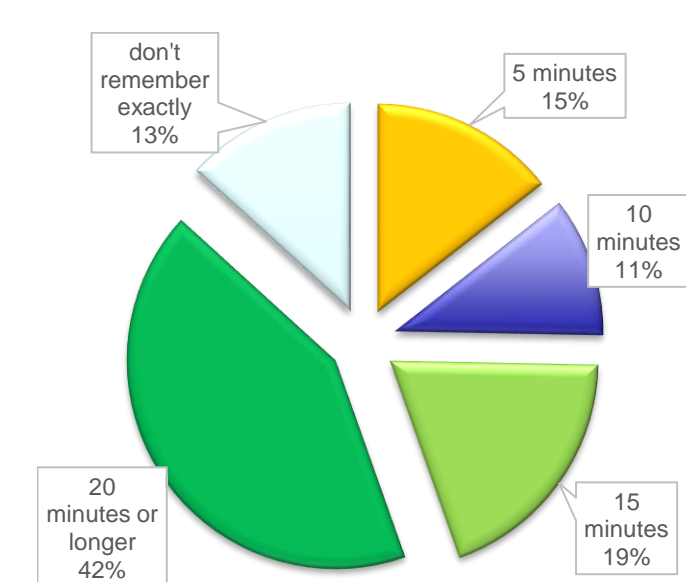


Fig. 5: Time for communicating initial diagnosis to patients

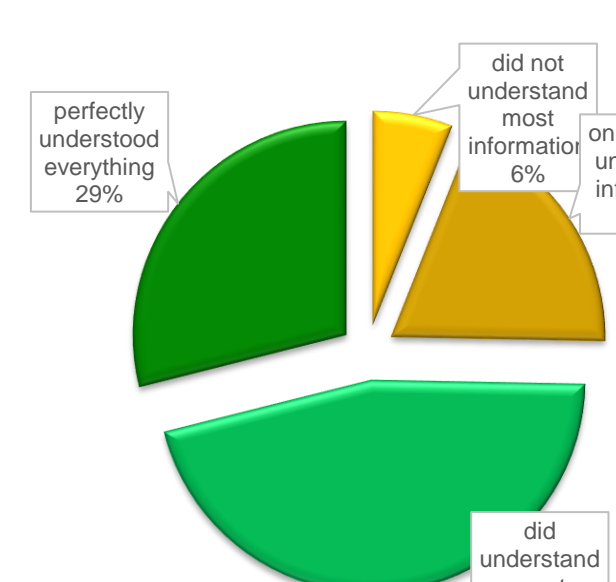


Fig. 6: Perception of initial diagnosis

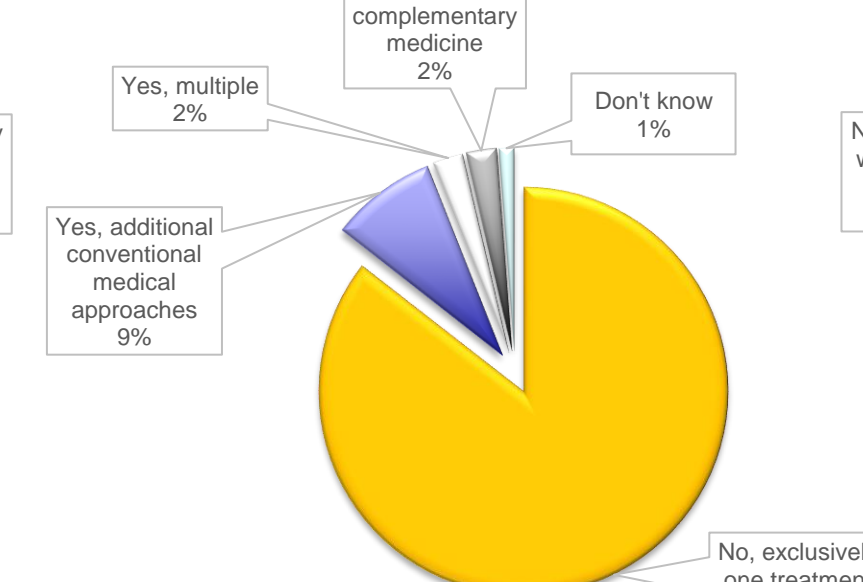


Fig. 7: Treatment offering at initial diagnosis

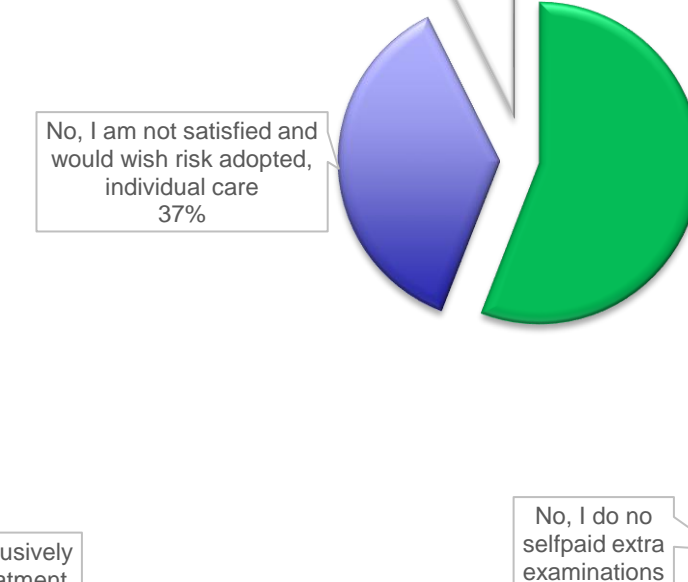
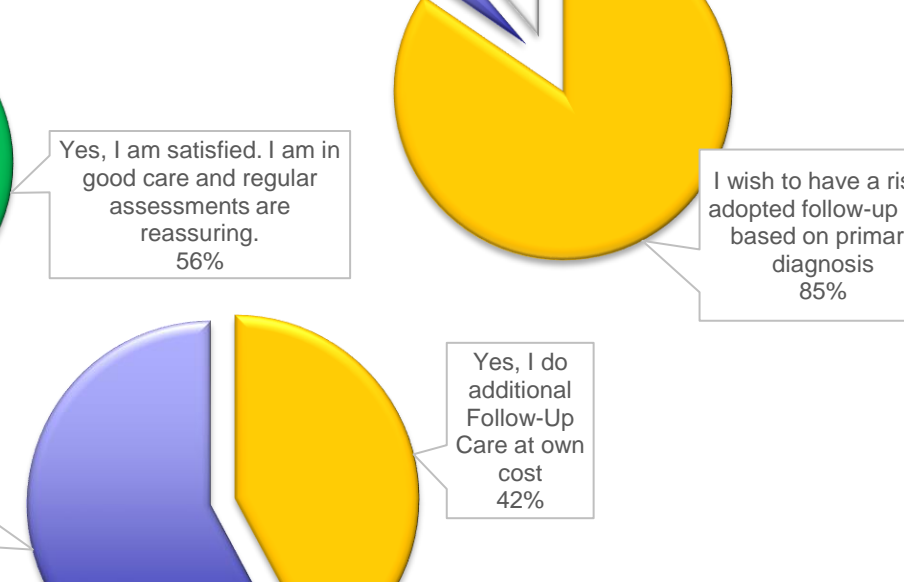


Fig. 8: Follow-Up Care Satisfaction

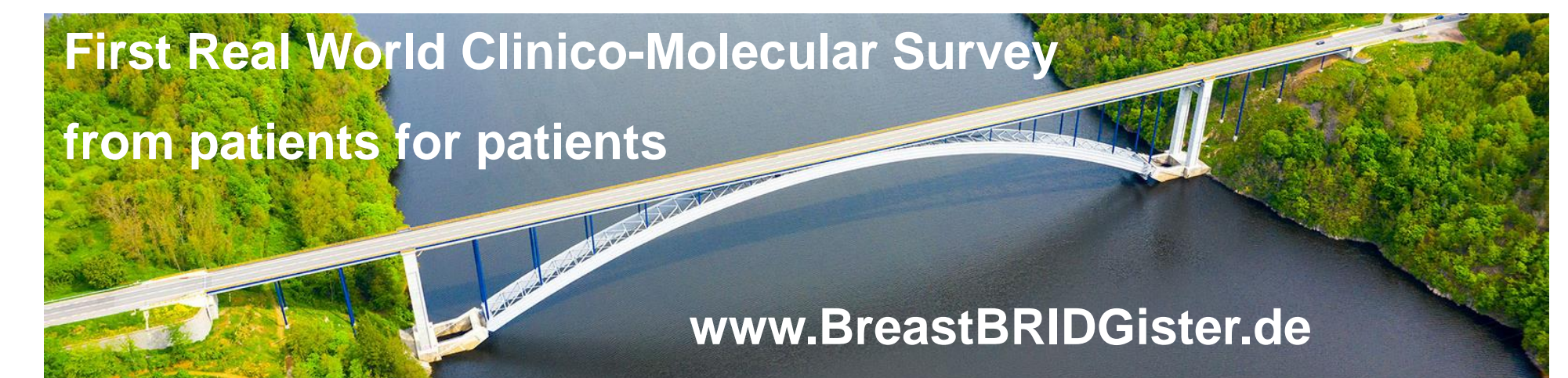


Results

Despite in depth complexity > 85% of patients completed the whole survey. Age distribution of the pilot cohort revealed comparably younger patient age (38% between 30-39 years, 40% between 40-49 years, 24% between 50-59 and 10% being above 60 years) and dominance of Triple Negative Patients (~39%) participating the online survey in the pilot cohort. 97% of patients were treated in certified breast centers (50% in larger centers of bigger towns, 15% in central clinics, 23% in university sites, 5% in local hospitals and 7% at office based doctors). Interestingly, 25% of patients did not or only partially understand their diagnosis and upcoming treatment. Time spent for communicating initial breast cancer diagnosis was less than 10 minutes for 25% of patients, while 13% did not remember. Exclusively one treatment option was discussed with 86% of patients. 78% have been informed about their initial breast cancer diagnosis in personal meetings, while 21% were informed by phone calls. 37% of patients had been informed about their patient rights. At preplanned interim analysis 38% of patients were lymphnode positive and 6% metastasized at initial diagnosis. 56% of patients were satisfied with their guideline conform follow-up-care, while 42% did pay for additional follow up care on their own. 85% of patients wished to have a risk-adopted, more individualized follow-up care.

Discussion

Patient centered Real World Experience Analysis with patients is feasible by decentral data capture and reveals needs and problems in patient communication, follow-up care and diagnostics. Subprotocols are planned to further explore adoption of new diagnostic & treatment opportunities in Real World.



Material & Methods

Establishing a cloud-based IT Platform enabling nationwide, decentral data entry using Climedo clinical trial software tools without the need of any commercial app utilities and therefore obeying DSGVO conform standards, an interconnected online platform integrating 36 interconnected surveys comprising >1.200 singular questions has been set up between 2020 and 2022 based on patient content elaboration & wishes. The questionnaires address all Real World experiences e.g. at initial diagnosis, during primary treatment and side effect management with complementary medicine, follow up care realities.

After 100 patients a preplanned statistical analysis has been performed to evaluate the feasibility of the patient oriented ePRO approach and demonstrate relevance of proof-of-concept results before entering international trial expansion. Descriptive analysis by Excel as well as Correlation analysis; Chi square and Partitioning tests using the SAS JMP® 9.0.0 software were performed