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Remote symptom monitoring for lung cancer patients: Lessons learned from the Lung AID Pilot Study

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Introduction and Objectives

- Digital solutions that identify changes in health status, flag them, and alert the patient's care team in a timely manner may complement existing approaches to monitoring and managing symptoms and thus improve health outcomes for treated patients
- In Germany, the 2019 Digital Healthcare Act allows for reimbursement of digital health prescriptions by the statutory health insurance when a positive impact on health-related outcomes has been shown
- Given the importance of emerging health technologies in patient care, the Lung Artificial Intelligence-Enabled Digital Solution (Lung AID) Pilot Study was designed to evaluate the feasibility of conducting a future evaluation study using remote symptom monitoring in real-world clinical settings
- Patient recruitment was challenging during study implementation; therefore, a qualitative analysis was conducted to identify and address enrollment barriers

Methods

- The Lung AID Pilot Study is a prospective, single-arm, observational study that planned to include 100 patients with metastatic non-small cell lung cancer (mNSCLC) at 10 German cancer centers implementing the KAIKU Health® platform
- The platform is an artificial intelligence (AI)-enabled digital remote symptom monitoring tool. It allows oncology patients to report their health status in real time to their healthcare providers (HCP), who can then take appropriate and timely action in response to any detected or predicted health status changes
- In response to the low enrollment rates, an initial investigator meeting was held to identify barriers and propose solutions, with additional meetings to maintain communication. Site visits were conducted to motivate site staff and identify site-level enrollment barriers
- The resulting information was categorized using a fishbone diagram for root cause identification. Fishbone diagrams are used to visualize different cause categories and identify possible causes contributing to a problem, which is represented on the horizontal arrow in the center of the figure. The vertical lines represent the identified cause categories. The branches pointing to these lines include supporting details

Results

- Problem statement: From January 2022 (when the first site was ready) to August 2022, the study had enrolled 13 of the targeted 100 patients. During that time, 5 out of 10 sites had not recruited any patients, even though sites were selected based on feasibility and the majority had been active for several months
- Identified barriers were categorized as communication/engagement with HCPs and patients, technological readiness by patients and sites, study adoption at sites, inconvenience of study design for patients and sites, and lack of eligible patients (**Figure 1**)
- Consequently, changes were made to the study design, including expansion of eligibility criteria, addition of 2 sites with expanded pre-implementation support, and enhanced patient education materials. Patient enrollment improved after these changes were implemented (**Figure 2**). However, enrollment remained low relative to the target
- Study enrollment closed early on June 30, 2023, with 47 patients enrolled. Patient characteristics are shown in **Table 1**
- Out of 12 sites participating in the study, 3 had previous experience with KAIKU Health®. On average, these three sites enrolled 8.3 patients, whereas the average number of enrolled patients across all 12 sites was 4.3
- While we observed concerns with PRO data collection, no specific issues were identified with the remote symptom monitoring tool

Figure 1. Fishbone analysis

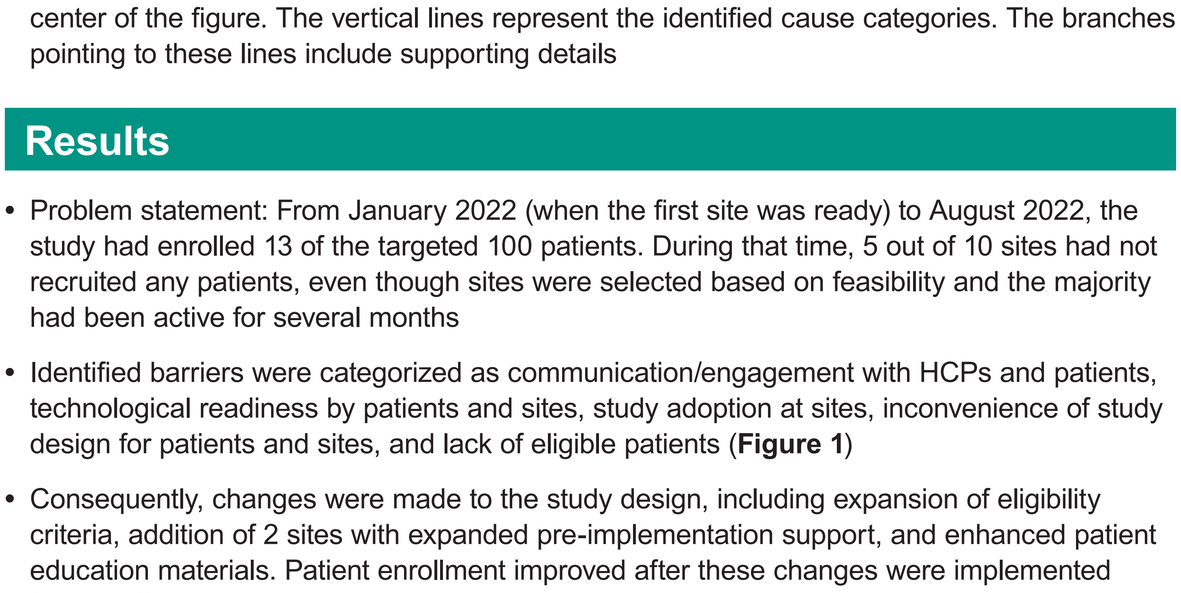

Figure 2. Monthly enrollment rate

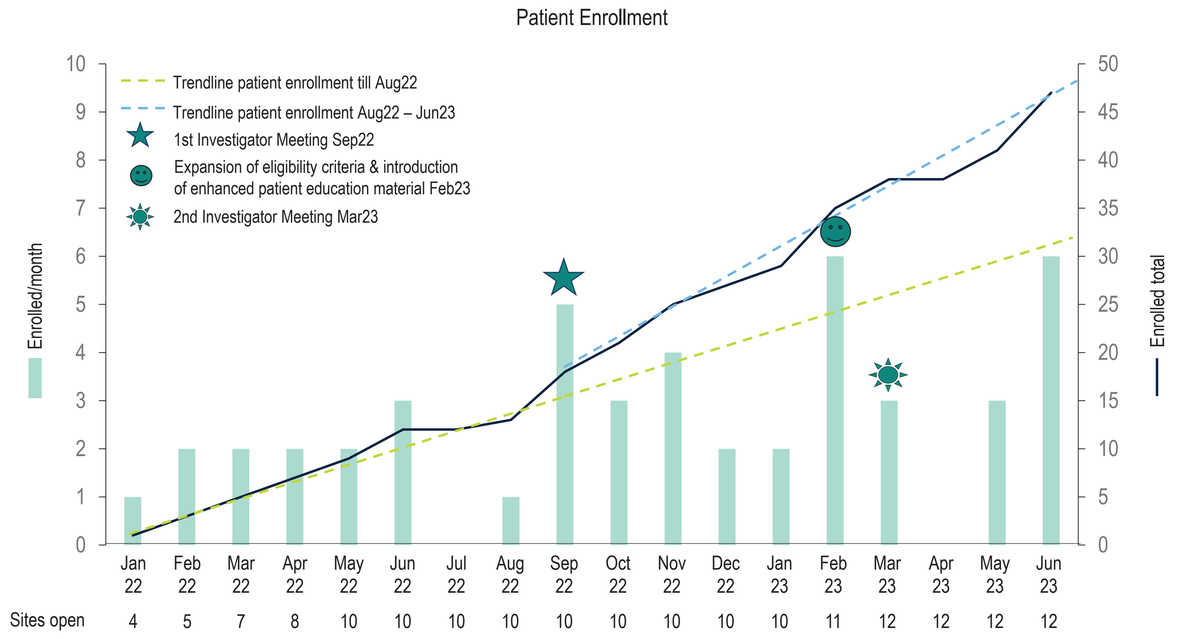

Table 1. Patient characteristics

Number of patients	47
Age (years)	**Median (range)**
Age at informed consent	64 (49-84)
Gender at birth	**n (%)**
Male	24 (51.06)
Female	23 (48.94)
Highest school degree	**n (%)**
Lower secondary school graduates	14 (29.79)
Secondary school graduates	20 (42.55)
High school graduates	9 (19.15)
No school degree at all	2 (4.26)
Missing	2 (4.26)
Pembrolizumab-based regimen	**n (%)**
Pembrolizumab monotherapy	18 (38.30)
Pembrolizumab + platinum + pemetrexed	19 (40.43)
Pembrolizumab + platinum + paclitaxel/nab-paclitaxel	10 (21.28)
ECOG performance status at baseline	**n (%)**
0	25 (53.19)
1	14 (29.79)
2	8 (17.02)

Conclusion

- By targeting the barriers around communication/engagement with HCPs and patients as well as broadening the study inclusion criteria, we observed increases in enrollment
- The following barriers were identified but could not be addressed:
  - Technological readiness by patients/sites
  - Study adoption at sites
  - Inconvenience of study design for patients/sites
- While it is feasible to implement a digital health application into the patient treatment journey, site engagement and patient recruitment/enrollment can be challenging. Early assessment and ongoing communication with sites and research teams are required to address emerging challenges
- Digital health research requires a flexible design and consideration of the real-world setting and potential barriers for site staff and patients. Addressing these implementation barriers early and on an ongoing basis is critical for future research

Abbreviations

AI, artificial intelligence; eCRF, electronic case report form; HCP, healthcare provider; HRQoL, health-related quality of life; Lung AID, Lung Artificial Intelligence-Enabled Digital Solution Pilot Study; mNSCLC, metastatic non-small cell lung cancer

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References:

Study Protocol

German Digital Healthcare Act, 2019 (*Digitale-Versorgung-Gesetz, DVG)*