Evaluation of a Self-Administered Smart Phone-Based Application as a Wellness Measure in a Clinical Trial of Zanubrutinib

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INTRODUCTION

HEALTH-RELATED QUALITY OF LIFE (HRQOL)

- A multidomain concept that represents the patient's general perception of the effect of illness and treatment on physical, psychological and social aspects of life *(FDA 2009)*

PATIENT-REPORTED OUTCOMES (PRO)

- Measures a patients health status as reported directly from the patient without added interpretation by a healthcare work or anyone else *(FDA 2022)*

- Patient-reported physical functioning and key symptoms are considered efficacy endpoints in the clinical trials by the regulatory and HTA agencies *(FDA 2018, EMA 2016)*
- Demand is increasing for improved methods of HRQoL measurements by the regulatory and HTA agencies

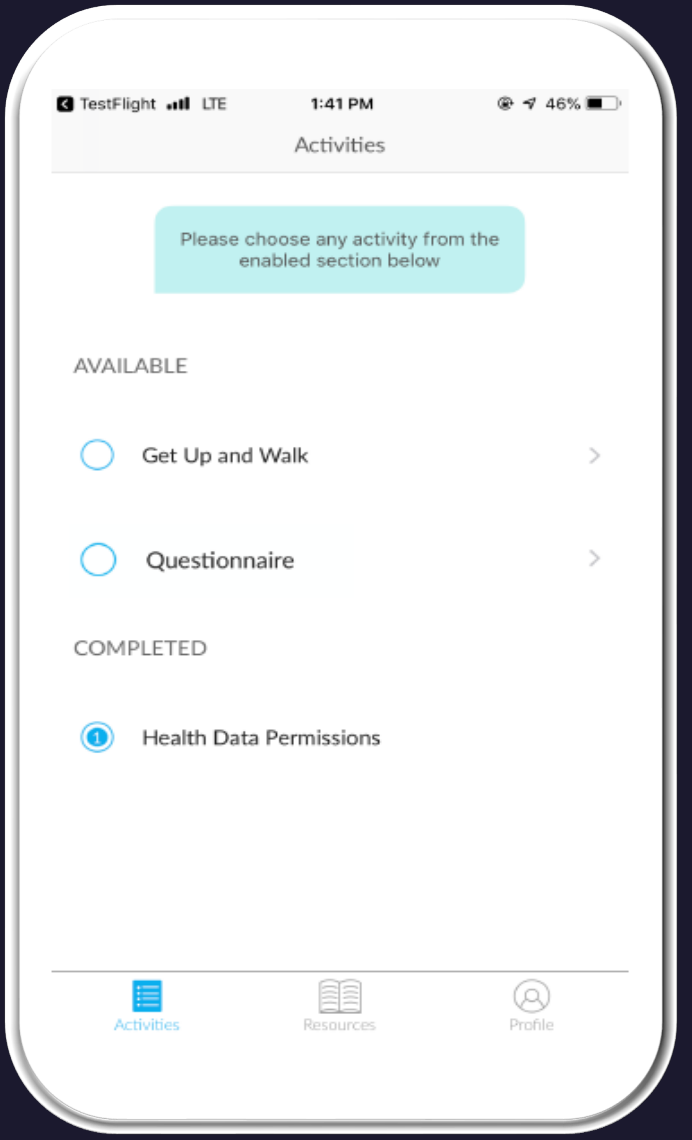
- Self-administered assessments via smart phone-based applications (apps) can gather patient wellness data
- In recent years technology-based assessment such as smartphone apps has been tested and implemented to collect data in clinical trials
- Potential advantages of app-based PROs: data can be collected in real time, remotely, better compliance, accuracy, completeness and cost-savings
- Data regarding feasibility of self-administered app utilization in clinical trials are limited

OBJECTIVES

- Exploratory analysis to evaluate the engagement and feasibility of using a voluntary device-based, self-administered wellness app as a supplemental tool to assess quality of life in clinical trial patients from study BGB-3111-215
- Study BGB-3111-215 (NCT04116437): phase 2 study including patients with B-cell malignancies treated daily with oral zanubrutinib

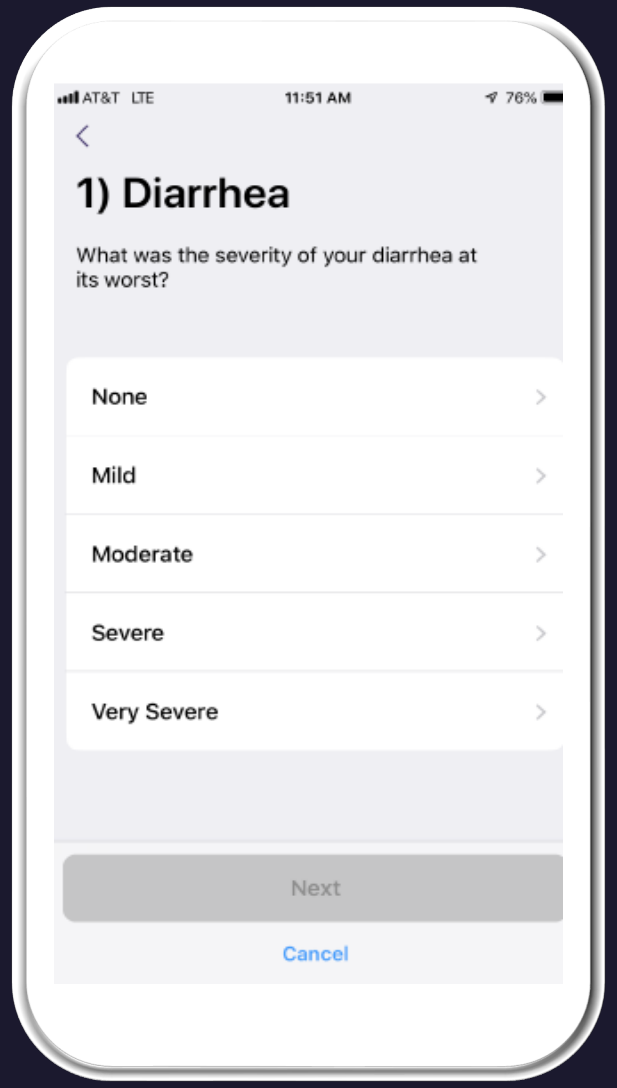
METHODS

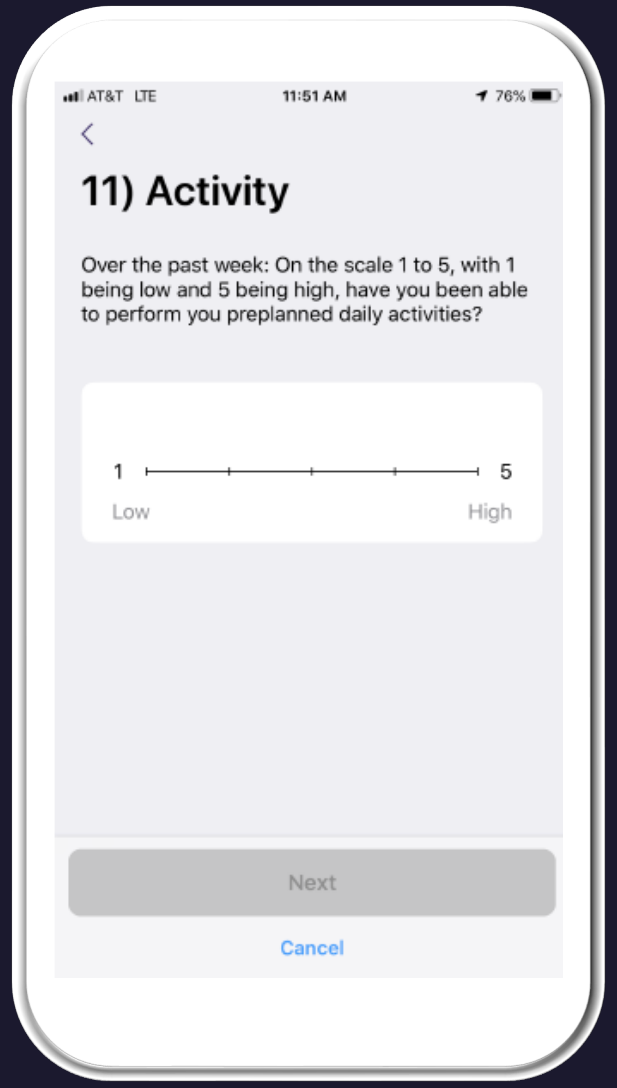
- Patients enrolled in the trial were invited to download and consent to use a voluntary device-based, self-administered activity and HRQoL questionnaire app *(Medable, California, USA)*
- The app included:
  - Self-administered questionnaire
  - 6-minute walk test
  - Passive activity tracking



Self-administered Questionnaire

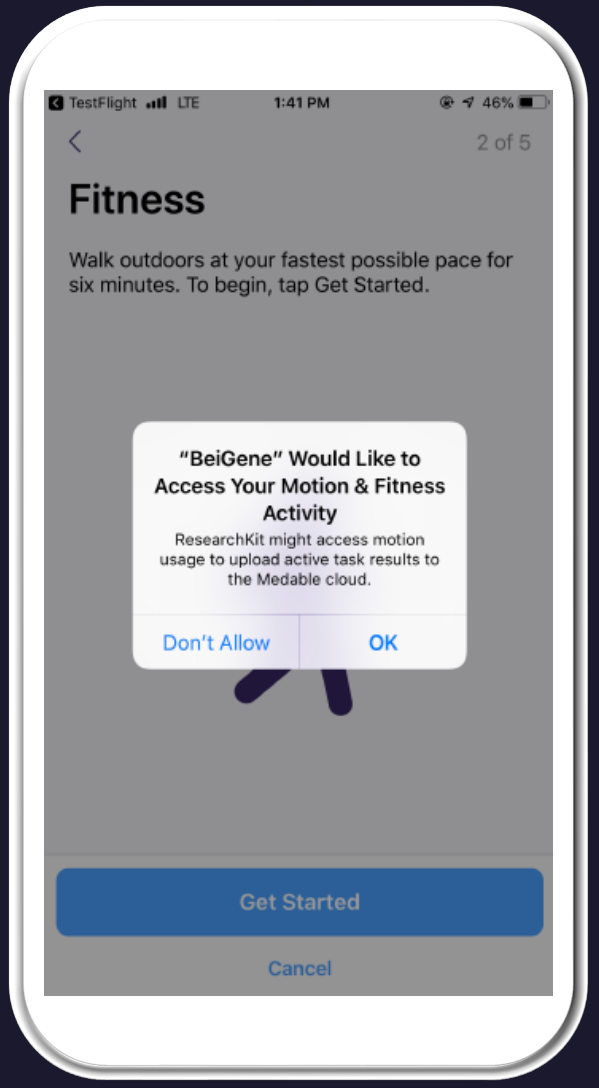
- A series of questions to assess patient health every week
  - Up to Week 13 — once per week
  - After Week 13 — once per 4 weeks until disease progression or end of study
- Results uploaded to a central database





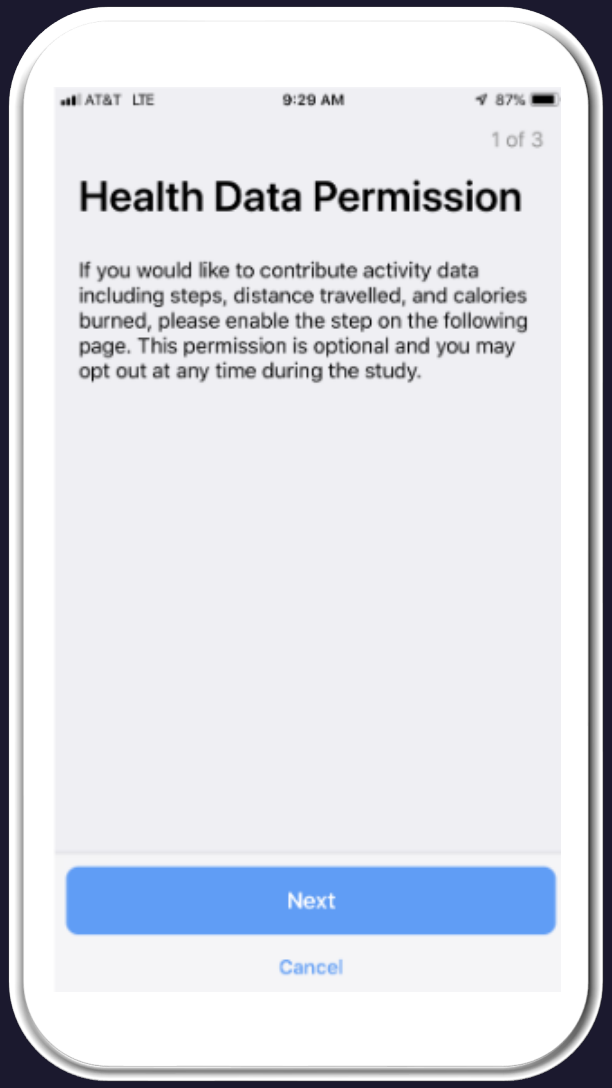
6-Minute Walk Test

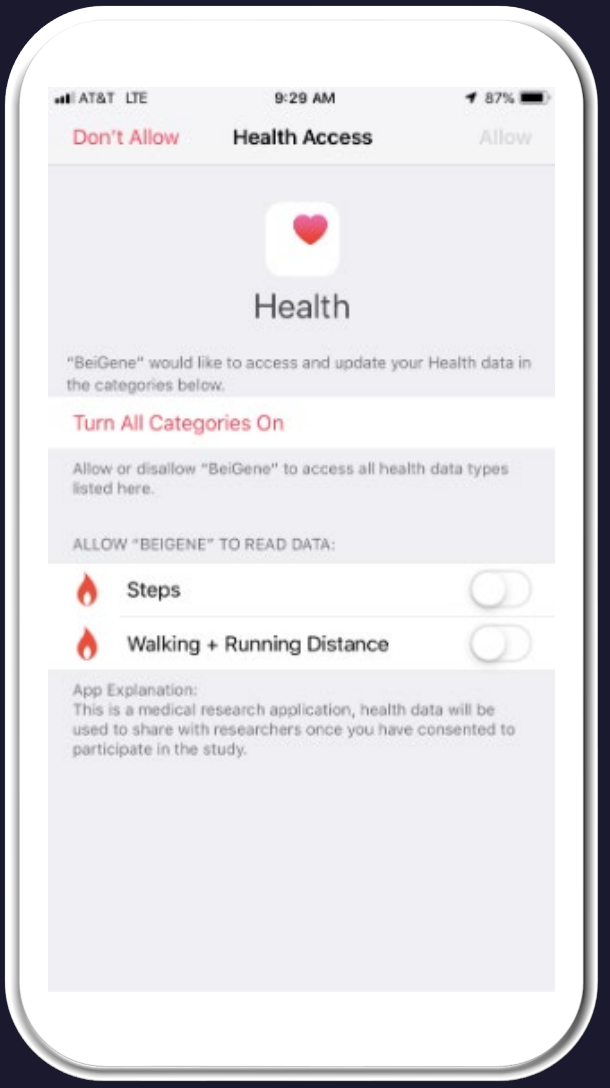
- Patients prompted to complete a 6-minute walk test (walk as far as they could for 6 minutes)
  - Up to Week 13 — once per week
  - After Week 13 — once per 4 weeks until disease progression or end of study
- The app collected information on:
  - Motion and fitness data
  - Distance traveled (the app does not view location data)



Passive Activity Tracking

- Step count and distance
- Collected continuously and summarized for each week





Feasibility Measures of App

- **Consent rate:** assessed by the percentage of patients who agreed to app use
- **Utilization rate:** assessed by percentage of patients who engaged with the app
- **Compliance rate:** assessed by actual versus scheduled engagements

RESULTS

App Consent Rate

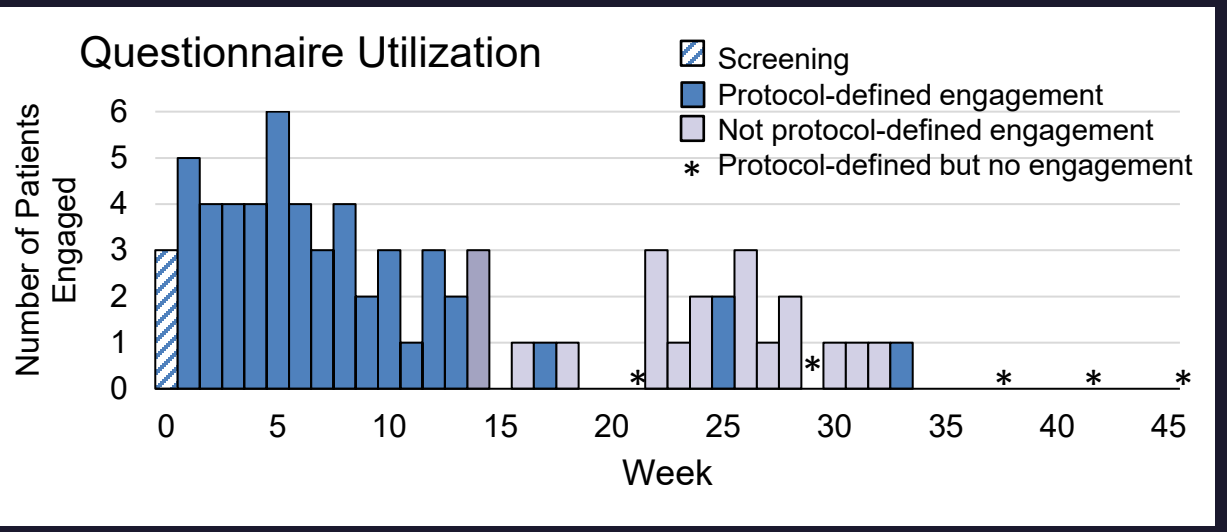
- As of 1 September 2022, 78 patients had enrolled in the study (median age=71 years)
- 20 enrolled trial patients consented to the app **(Consent Rate=26%)**

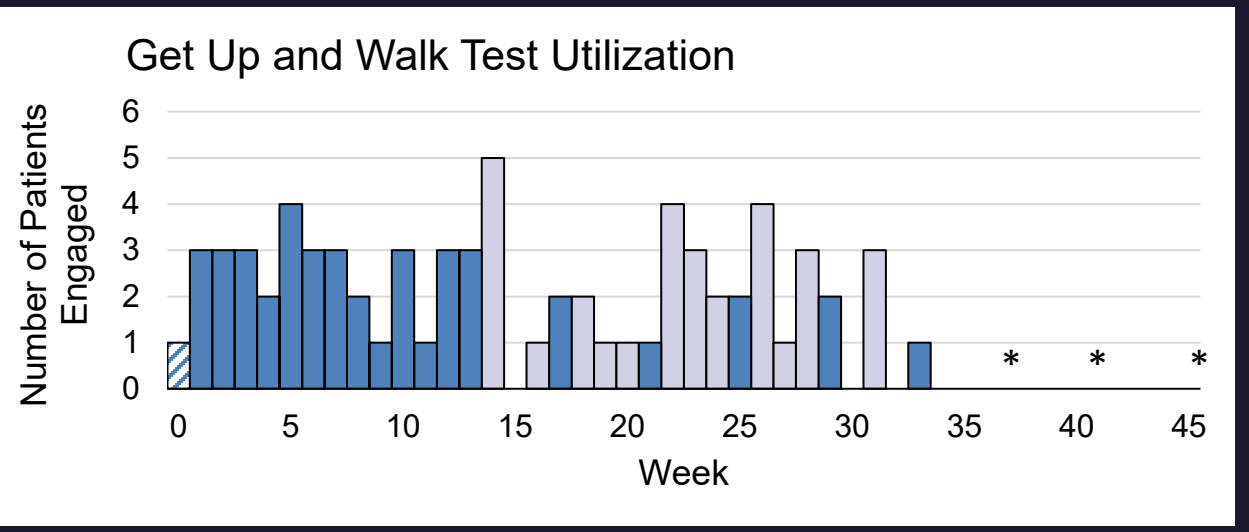
	Patients who consented and engaged (n=11)	Patients who consented and did not engage (n=9)	Patients who did not consent (n=58)	Total (N=78)
Male sex, n (%)	6 (54.5)	6 (66.7)	31 (53.4)	43 (55.1)
Age, years, median (range)	65 (49, 73)	71 (63, 87)	73 (50, 91)	71 (49, 91)
Race, n (%)				
White	10 (90.9)	8 (88.9)	54 (93.1)	72 (92.3)
Black or African American	0	0	1 (1.7)	1 (1.3)
Asian	1 (9.1)	0	0	1 (1.3)
Multiple	0	1 (11.1)	0	1 (1.3)
Not reported/Unknown	0	0	3 (5.2)	3 (3.8)
Ethnicity, n (%)				
Not Hispanic	11 (100.0)	9 (100.0)	56 (96.6)	76 (97.4)
Hispanic	0	0	2 (3.4)	2 (2.6)
ECOG PS, n (%)[a]				
0	9 (81.8)	6 (66.7)	31 (53.4)	46 (59.0)
1	2 (18.2)	3 (33.3)	25 (43.1)	30 (38.5)
2	0	0	2 (3.4)	2 (2.6)

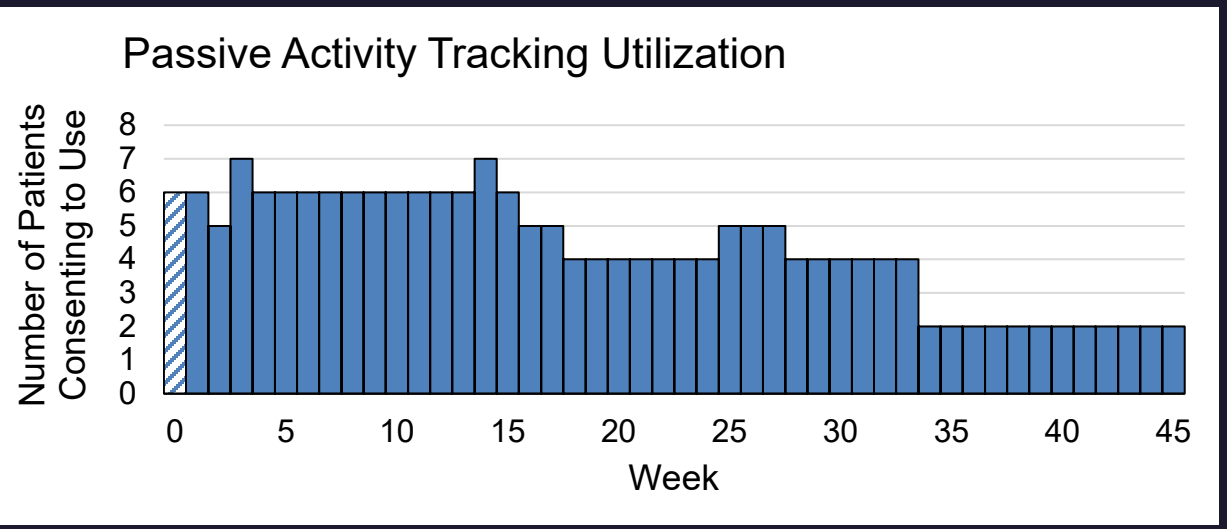
Disease type	Patients, n % N=78
CLL	51 (65)
WM	12 (15)
SLL	8 (10)
MZL	4 (5)
MCL	3 (4)

App Utilization Rate

- 11 patients (median age=65 years) engaged with the app at least once (**Utilization Rate=14%**)
- Questionnaire engagement occurred a median of 2 times (range, 1-17) and a median of 7 times (range, 1-15) for the walk test
- 4 patients engaged with the questionnaire and 6 patients engaged in the walk test beyond Week 12
- Passive activity was collected for 8 patients beyond Week 12



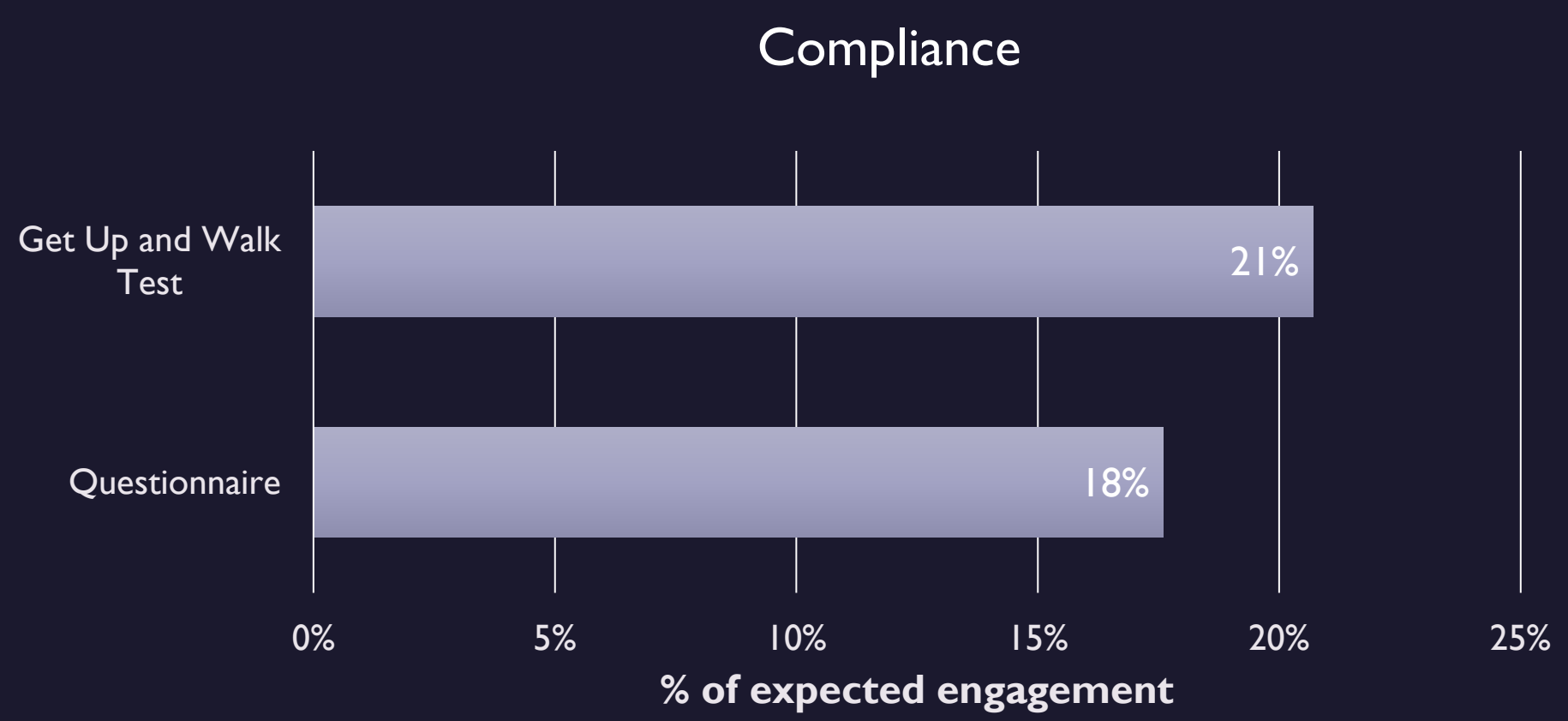




Patients, n (%)	Before Week 12	After Week 12
Patients enrolled	78 (100)	
Patients consented	20 (26)	
Any app engagement	11 (14)	11 (14)
Questionnaire	11 (14)	4 (5)
Walk Test	7 (9)	6 (8)
Passive Activity	10 (13)	8 (10)

App Compliance Rate

- Among patients who engaged the HRQoL questionnaire and walk test, compliance rates were 18% and 21%, respectively



CONCLUSIONS

- This exploratory analysis showed that a subset of clinical trial patients was willing to participate in the self-administered QoL questionnaire and activity tracker
- Further comparison of app results and clinical trial findings are ongoing to explore factors affecting utilization and compliance rates

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