VIRTUAL STUDY YIELDS HIGH COMPLIANCE & RETENTION RATES

EXECUTIVE BRIEF

BACKGROUND

Clinical research studies involving repeated patient reported outcome measures (PROs) face several challenges. Patients may fail to complete individual PROs, whether at all or within a specified time (i.e., reduced **compliance**). Patients may cease participating in a study altogether, dropping out before all study procedures are completed (i.e., reduced **retention**). Sponsors must consider strategies to maximize participant retention and compliance to avoid loss of PRO data relevant to study endpoints and to avoid financial and operational burdens associated with participant loss to follow-up (e.g., needing to enroll additional patients to capture sufficient safety follow-up data).

Through Datacubed Health's Linkt app, participants can easily complete PROs via their smartphones. Several features are available within Linkt to assist study staff with ensuring high participant retention and compliance, including configurable reminders to complete instruments. Linkt leverages behavioral science to sustain high compliance and retention rates, with several tiered motivational elements for short, medium, and long-term studies.

PRESENT STUDY

A study was conducted by a large academic medical center in New York City. The study enrolled 124 participants located across the United States. Participants downloaded the Linkt app onto their personal smartphone devices. Through Linkt, participants completed a daily diary and other electronic patient reported outcome (ePROs) for 55 days. At least one instrument was deployed each day. Over the course of the complete study subjects were asked to complete a total of 104 instruments.

Participants ranged from 18-64 years of age at time of enrollment. Participants were 59.35% female and 40.65% male. Also, 50% of participants spoke a language other than English at home, although all instruments for this study were delivered in American English. Most participants were college educated, employed full time, and participated in the study with an iPhone (See Table 1).

RETENTION AND COMPLIANCE

Overall, 93.5% of participants (N=116) were retained for the entire 55-day duration of the study (Figure 2). In this study, *all fully retained participants had a compliance rate of 100%* (Figure 3). Eight participants withdrew from the study early. The average participant who withdrew from the study did so after 23 days, or after completing approximately 50% of the study. Time-to-withdrawal was strongly correlated with compliance rate (R=0.98), such that participants who stayed in the study longer

were more compliant (Figure 4). There were no effects of demographic variables (e.g., age, gender, education, employment status, etc.) on overall retention (Table 2).

TABLE 1: SAMPLE DEMOGRAPHICS	N	PERCENT
AGE GROUP		
18-24	38	30.89%
25-34	45	36.59%
35-54	31	25.20%
55+	9	7.32%
GENDER		
Female	73	59.35%
Male	50	40.65%
PHONE OPERATING SYSTEM		
iOS	88	70.97%
Android	36	29.03%
EMPLOYMENT		
Employed full-time	41	33.06%
Student, full-time	31	25.00%
Employed part-time	24	19.35%
Unemployed, looking for work	16	12.90%
Unemployed, not looking for work	6	4.84%
Other	6	4.84%
EDUCATION		
Some high school	2	1.61%
High school graduate	11	8.87%
Some college	28	22.58%
Associate degree	10	8.06%
Bachelor's degree	49	39.52%
Graduate degree	23	18.55%
Other	1	0.81%
LANGUAGE SPOKEN AT HOME		
English	62	50.00%
Other	62	50.00%
RACE		
Asian	48	38.71%
White	41	33.06%
Black or African American	22	17.74%
Other	9	7.26%
Multiple Races	4	3.23%

Compliance was defined as a proportion: the number of instruments completed as a percentage of the number of instruments delivered in the Linkt App. Looking across all participants (retained and lost), on average, the compliance rate was 96.2% for study measures completed via Linkt. The overwhelming majority of participants (N=116; 93.5% of participants) had a perfect compliance rate of 100% (Figure 3). For the 8 participants who withdrew early and did not complete all the study instruments, compliance ranged from 18.9%-78.4%. There were no effects of demographic variables (e.g., age, gender, education, employment status, etc.) on overall compliance (Table 2).
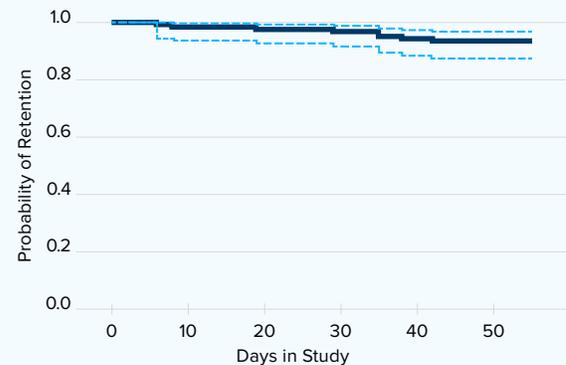
FIGURE 2

KAPLAN-MEIER ESTIMATE FOR STUDY RETENTION

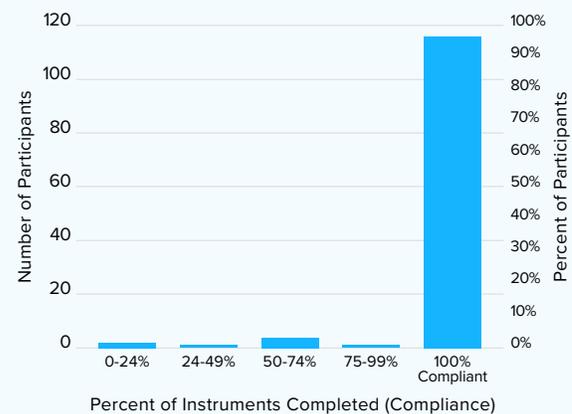FIGURE 3

COMPLIANCE BY NUMBER AND PERCENT OF PARTICIPANTS

TABLE 2: RETENTION AND COMPLIANCE DID NOT VARY WITH PARTICIPANTS' DEMOGRAPHIC BACKGROUNDS

DEMOGRAPHIC VARIABLE	COMPLIANCE			RETENTION		
	TEST STATISTIC	p VALUE	SIGNIFICANCE	TEST STATISTIC	p VALUE	SIGNIFICANCE
Age Group	$F(120,1)=0.70$	0.40	*NS*	$F(120,1)=0.45$	0.50	*NS*
Gender	$t(107.95)=-0.02$	0.87	*NS*	$t(100.39)=-0.04$	0.97	*NS*
Phone Operating System	$t(62.10)=0.02$	0.87	*NS*	$t(58.38)=0.02$	0.99	*NS*
Employment Status	$F(121,1)=0.72$	0.40	*NS*	$F(121,1)=1.28$	0.26	*NS*
Education	$F(121,1)=0.75$	0.39	*NS*	$F(121,1)=0.35$	0.56	*NS*
Language Spoken at Home	$t(120.1)=-0.10$	0.92	*NS*	$t(117.66)=-0.27$	0.78	*NS*
Race	$F(121,1)=0.01$	0.54	*NS*	$F(121,1)=0.13$	0.72	*NS*

FIGURE 4

RELATIONSHIP BETWEEN RETENTION AND COMPLIANCE

116 participants were 100% compliant and retained until the study end
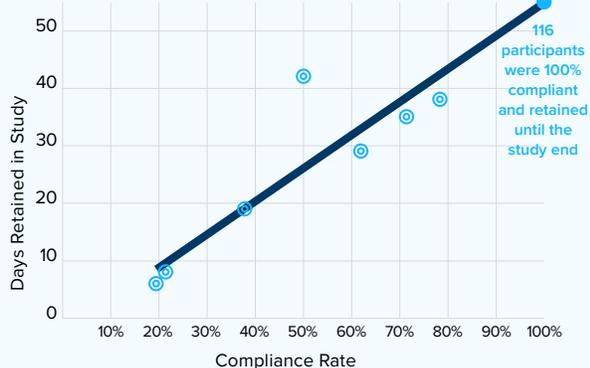
CONCLUSIONS

The majority of participants in the present study were 100% compliant and retained through study end, completing a minimum of one instrument per day, or 104 instruments total, for 55 days. Deploying daily diary and ePRO measures via Linkt results in high retention and average compliance rates (93.5% and 96.2%, respectively) and can even achieve 100% compliance amongst the retained cohort. Linkt was well tolerated across participants of diverse demographic backgrounds (e.g., age, sex, race, socioeconomic status, language). When deployed with standard engagement and gamification features, studies using the Linkt platform can expect to achieve high retention and compliance rates, across diverse participant populations.