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Empowered Patients, Faster Cures

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Founder and CEO

Current State: Patients are Passive Consumers

- Clean
- Structured
- Limited
- Expensive
- Time Consuming
- Proprietary

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THREE BIG TRENDS

Point of Care is Shifting

95% - cellphone

77% - smartphone

20% - online access

75% - Physicians

75% - Willing to use

Source: 2018 Pew Research
2018 Physician Practice Survey

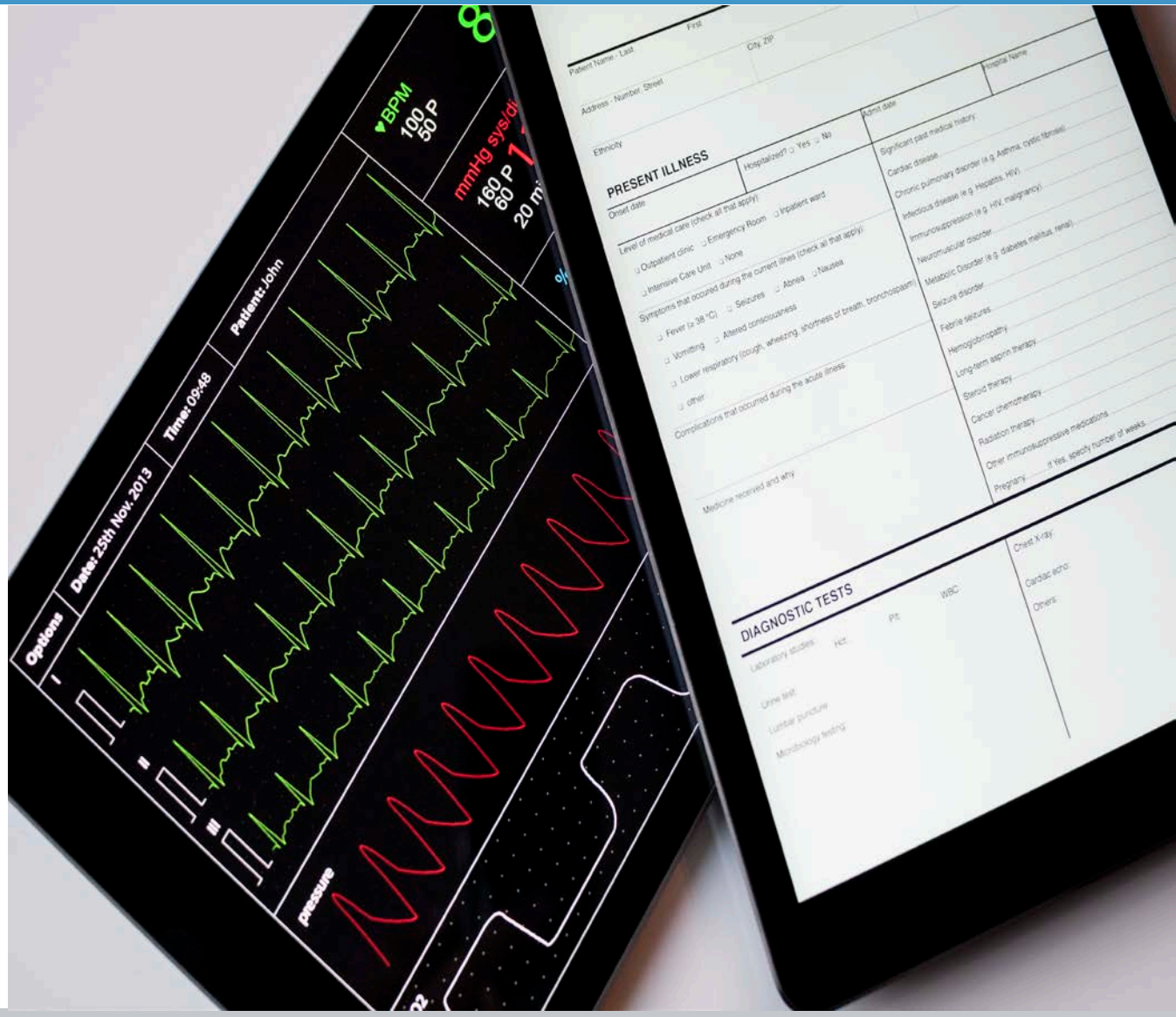
Data is abundant but Siloed & Noisy

83% - EHR Adoption

Variety of Data beyond the HER

Interoperability

Security



Data Access is More Important than Ownership

Access

Integrate

Mine

New Players

-Amazon

-Apple

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Big Opportunity: Patients as Partners

Patients are Ideal Aggregators of RWD

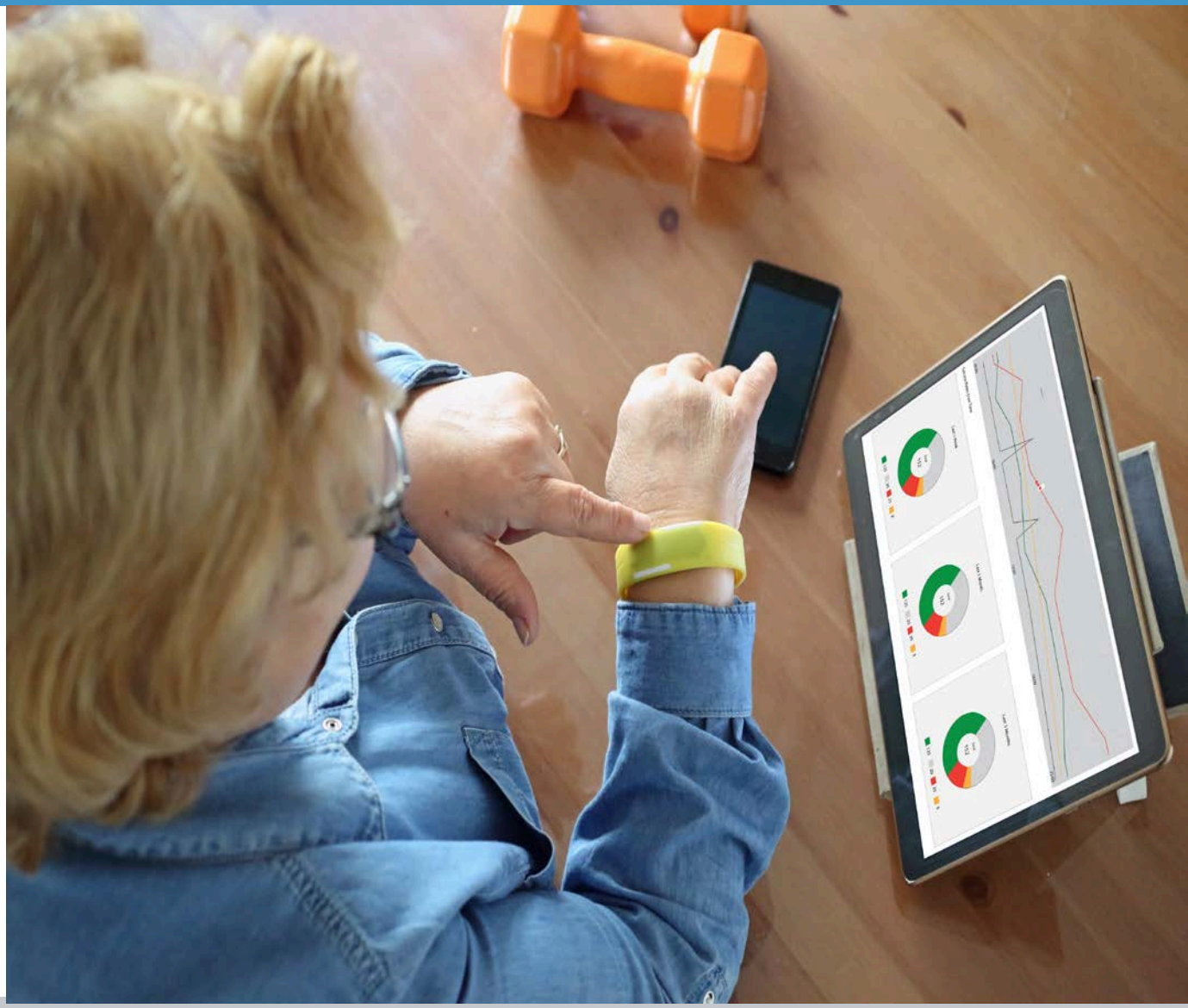
Own the data

Access to data

96% - willing to share

Security

Trust



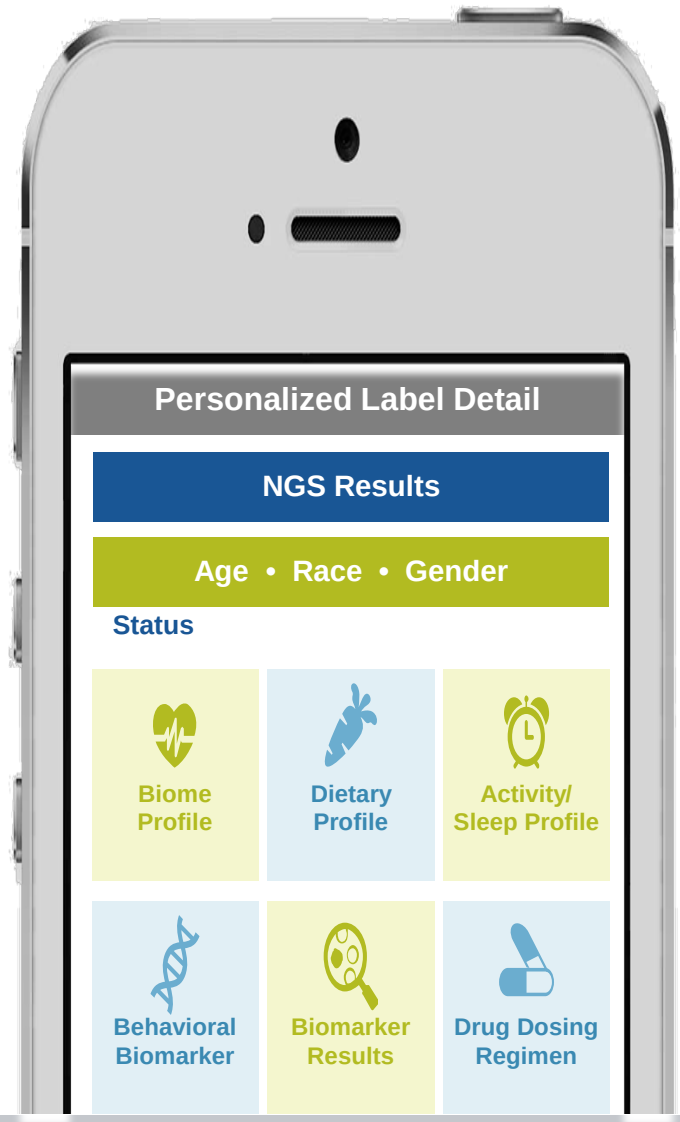
Patients will Generate RWI to inform new Endpoints

Meaningful Endpoints

Influence Design

Decision Making

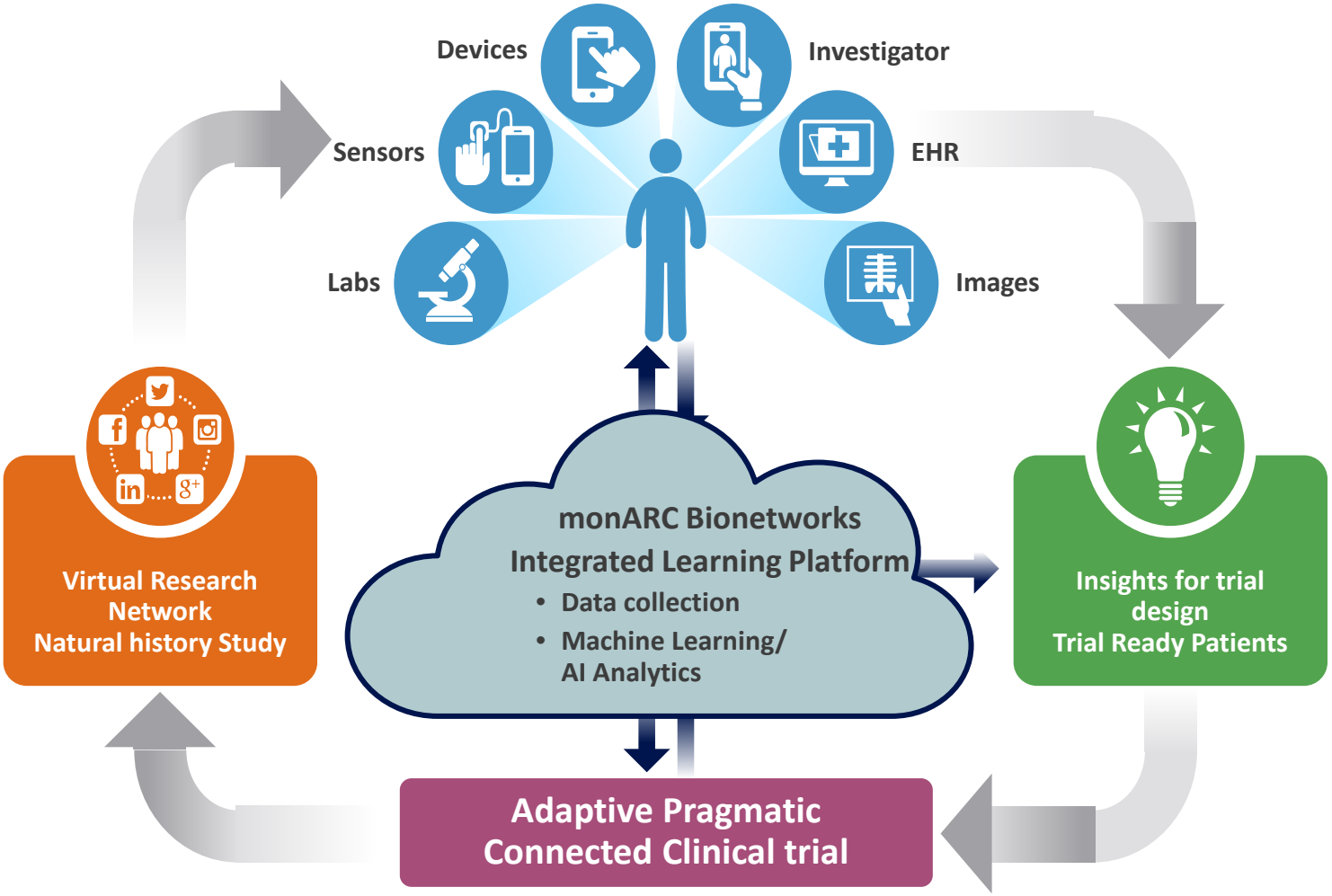
Continuous RWD Trial => Dynamic Label



Direct to Patient

Personalization of data to inform decision making at the point of care will be an expectation.

moARC's Integrated RWD Learning Platform



IRB Approval to Published Poster in 4 months

AN OBSERVATIONAL STUDY TO BETTER UNDERSTAND THE ADHERENCE AND USE OF HOME-BASED DIGITAL DEVICES TO MEASURE DISEASE-RELEVANT OUTCOMES IN PATIENTS WITH IDIOPATHIC PULMONARY FIBROSIS AND TO ASSESS FEASIBILITY FOR FUTURE STUDIES

Switzer, T[1]., Stem, K[3]., Nagra, S[3]., ., Adamis, H[2]., and Belloni, P[1].
[1]Genentech Inc., South San Francisco, CA; [2]Roche, Basel, Switzerland; and [3]monARC Bionetworks, Inc., Palo Alto, CA

BACKGROUND & INTRODUCTION

- Idiopathic Pulmonary Fibrosis (IPF) is a disease with unpredictable progression rates and debilitating symptoms that include fatigue, breathlessness and dry cough.
- Estimated Median survival is 3-5 years after diagnosis.
- Assessment of IPF progression is typically performed within the clinic and clinic visits are not frequent enough to capture progression in real time.
- Measuring disease progression and treatment effect along with assessing the impact of disease on patient's daily life is currently limited to instruments that are used in the clinic
- Daily symptom diaries have been used, but rely on patient recall and are limited to data collection on specific times and days.
- To date, home-based digital devices have only been utilized in single center studies assessing the use of home spirometry to detect disease progression associated with IPF but not in clinical trial research.
- Digital patient friendly tools have the potential to reduce patient time and travel burden to trial centers while collecting greater continuous insight into the progression and management of IPF in the home setting.
- Data on the usability, wearability, and utility of home digital devices to collect disease and treatment symptoms, will inform and enable the planning of future virtual clinical trials in IPF.
- This study GA39830 was a feasibility study designed to evaluate the use and adherence of home-based digital devices (spirometer, wearable activity and sleep monitor (watch), wireless body weight scale, and an iPhone with an app to assess common disease symptoms) to collect clinically relevant data in IPF patients

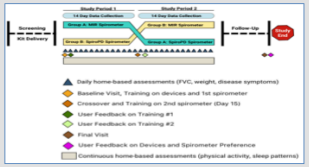
Objectives

Primary Objective
- To evaluate the feasibility of using digital devices to collect clinically relevant data in Idiopathic Pulmonary Fibrosis (IPF) patients in the home.

Secondary objectives
- To assess patient usability collecting :
  - daily spirometry data using a portable spirometer
  - continuous activity and sleep data using a wearable activity tracker
  - daily weight using a wireless scales
  - disease and treatment symptoms on daily diary app
- To qualitatively assess patient spirometer device preference

METHODS

- Patients with IPF (n=10, 40% male, median age 66.5 yrs with range of 55-81 yrs) were randomized at baseline to receive either of two hand-held spirometer devices: PMD Healthcare SpiroPD v2.0 (SPIRO) or the Medical International Research SpiroBank II Smart INT 1.3 (MIR).
- On Day 14, patients switched from the first spirometer to the second spirometer and the monitoring was continued for an additional 14 days.
- At the end of the study, patients will rate their spirometer device preference and provide reasons for their preference.
- Subjective feedback data was collected through 3 phone interviews with each of the participants. Interviews were conducted on Day 2 (after Baseline visit and training on devices and first spirometer), Day 15 (after crossover and training on second spirometer), and Day 28 (the last day). On Day 28, each subject provided subjective feedback including their experiences with both spirometer devices and detailed feedback regarding use of the watch, weight scale, and iPhone app.



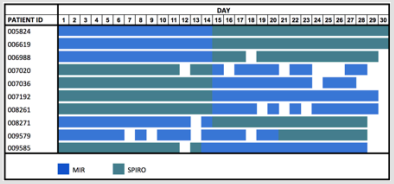
Inclusion criteria
- Able and willing to provide electronically signed informed consent
- Age ≥ 40 years
- Confirmed diagnosis of IPF based per ATS standards
- Home-based internet access via Wi-Fi connection
- Subject is mobile/ambulatory and not hospitalized for IPF

Exclusion Criteria
- Any other significant disease that would impair or risk the study subject's full participation in the study
- History of alcohol, drug, or chemical abuse that would impair or risk the study subject's full participation in the study
- Requirement for continuous medical care and assistance, or limited ability to self-care that would impact the ability of the patient to participate in the study or perform the study-related assessments.

RESULTS

Patient Adherence

	MIR	SPIRO	Activity	Sleep	Weight	Symptom	Adherence across all Activities
Mean	89.86	97.85	86.80	79.49	69.58	90.95	85.76
Median	96.43	100.00	100.00	91.43	67.38	92.86	90.18
Standard Deviation	13.44	3.47	28.23	28.16	21.94	10.54	11.69
Range (High)	100.00	100.00	100.00	93.10	100.00	100.00	96.55
Range (Low)	60.00	92.31	14.29	7.14	35.71	68.97	60.95



Within Patient In-Home Spirometry Reproducibility

	Median		Median SD (L)		Median Coefficient of Variation (%)	
	MIR	SPIRO	MIR	SPIRO	MIR	SPIRO
Median	1.94	1.93	0.12	0.14	6.30	7.00
Standard Deviation	0.82	0.72	0.06	0.17	2.66	10.81
Range High	4.10	3.73	0.22	0.62	9.12	36.58
Range Low	1.34	1.34	0.04	0.06	2.74	2.07

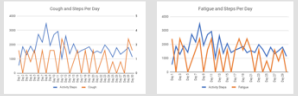
Historical In-Clinic vs In-Home Spirometry

	Elapsed Time since Clinic FVC	Clinic vs Home Spirometer Difference (L)	
	Days	MIR	SPIRO
Median	169	-0.38	-0.36
Standard Deviation	112	0.27	0.33
Range High	459	-0.13	-0.06
Range Low	57	-1.04	-1.08

Subjective Outcomes:

- Participants preferred daily single blow spirometry daily over daily multiple blow spirometry
- Participants prefer to receive output results post spirometry test
- Most participants found the process of recording their symptoms in a mobile app to be easy, quick, and straightforward.
- All 10 participants reported that they had no issues in using the app each day
- "Recording the symptoms in the app was fun"
- "It was interesting for the patient(s) to track their own symptoms over time"
- 9 out of 10 participants reported they would be interested in participating in a future study of longer duration

IPF Symptoms vs Steps per Day



Cough severity, shortness of breath, fatigue, nausea and diarrhea were recorded daily directly from the patient with a mobile app. Representative graphs from a single subject across 4 weeks show inverse relationship between cough, SoB and steps and increased steps associated with fatigue

CONCLUSIONS

- High Patient Adherence rates demonstrates that it is feasible and reliable to use digital tools for home based collection of clinical relevant data from patients with IPF over a 30 day period.
- Reliable reproducibility of repeated FVC measurements within a single IPF patient using in home spirometry was similar across both spirometers and similar coefficient of variation was reported by previous studies in daily home based spirometry for health subjects, COPD patients, and IPF patients.
- Home Spirometry underestimated the FVC Value compared to historical in-clinic FVC measurements. This decrease could be due to different tools or disease progression.
- Subjective interviews with patients indicated that patients preferred to blow less frequently, liked when data was shared with them and overall enjoyed tracking their data using a mobile application.
- For a few patients sleeping with the watch was difficult which makes it a difficult form factor to use for long periods of time.
- Daily step account using the watch was feasible and shows possible correlation to IPF symptoms. However, a larger sample size and longer observation period is needed.

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Big Change Requires Incentives

Next Generation Drug Development Needs

Incentives for

- Data Sharing across researchers/sponsors
- Novel Endpoint Development

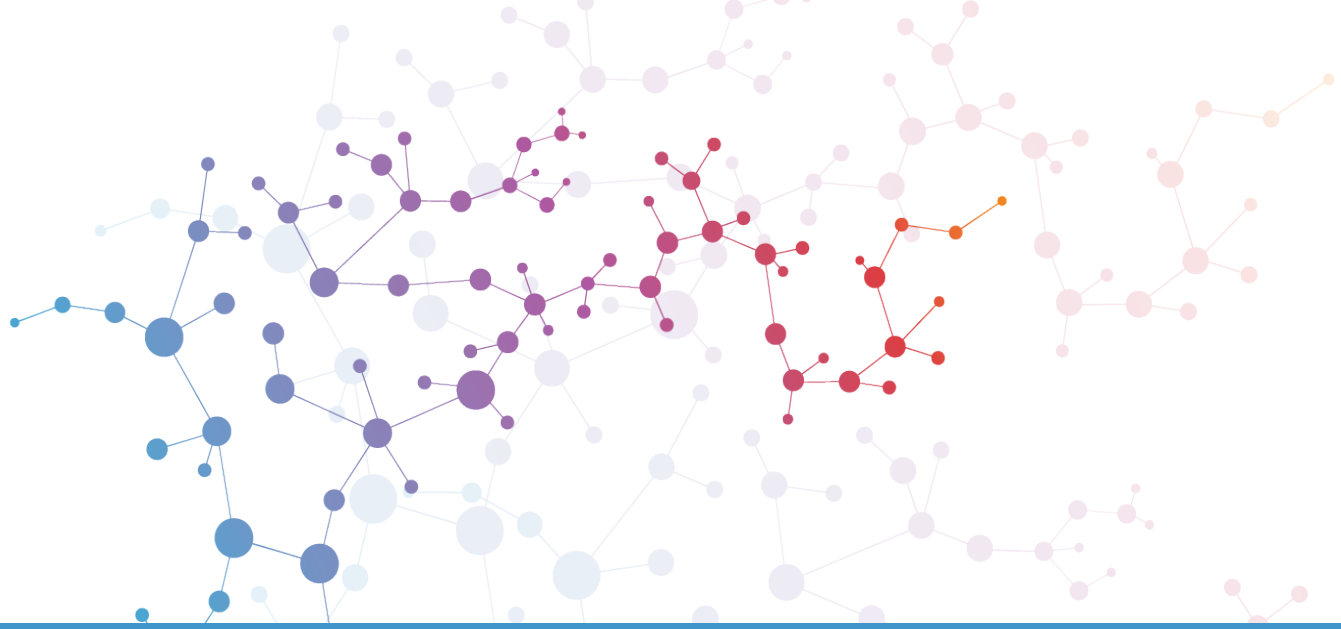
Improved Legislation to broaden access state borders

- State laws are limiting virtual trial capabilities
- Investigational Drug Shipment across borders

New Capabilities with non-traditional partners

Social networking, mobile devices, user experience, IOT, AI, security and cloud infrastructure for big data storage and analytics

Bold Partnerships with Patients



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Thank you

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