

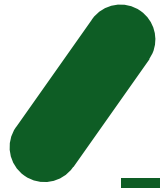
Patient and Public Involvement(PPI) and Pharmaceutical Development Through Open Innovation Processes: Recent Activities

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Contents

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- Patient and Public Involvement during the COVID-19 Pandemic
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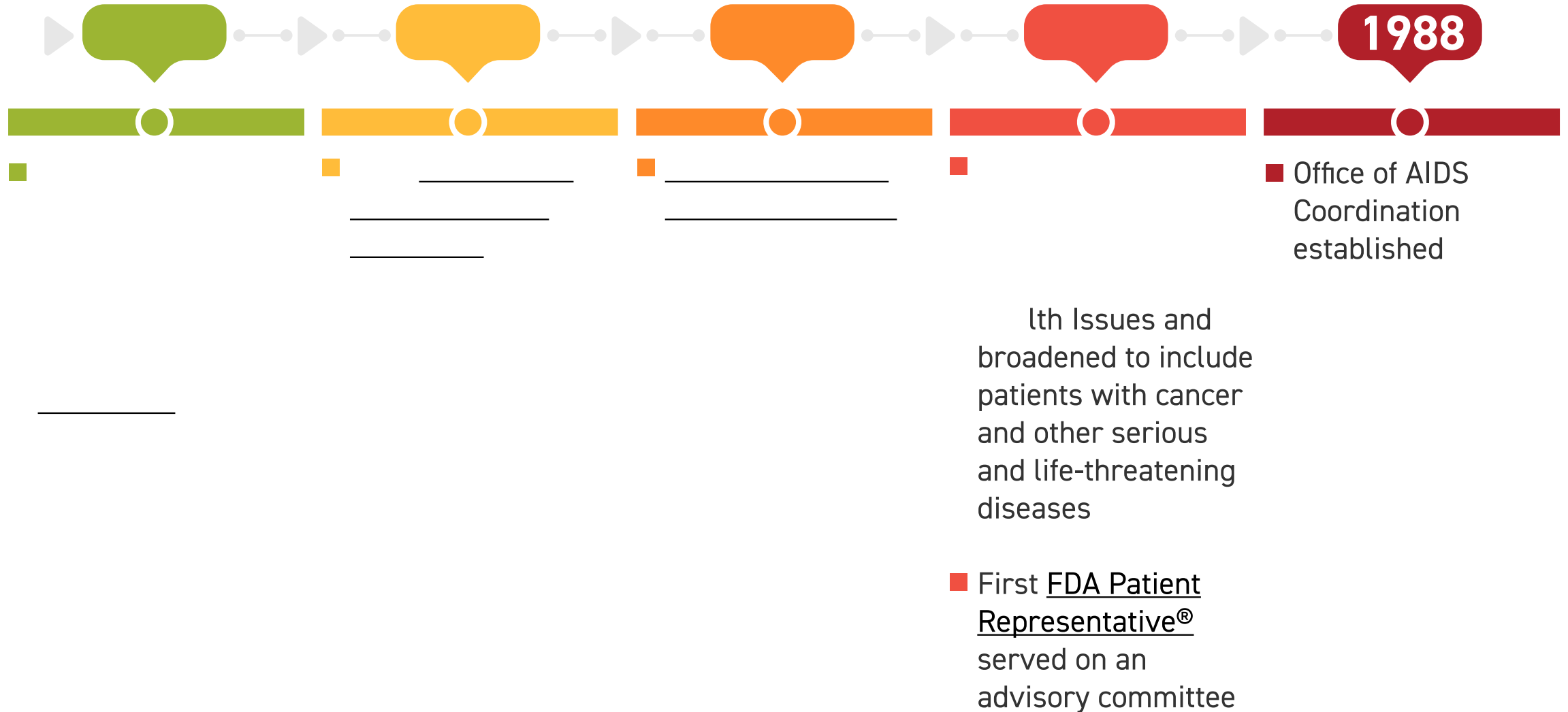
Introduction: “Patient Public Engagement”



- AIDS Coalition to Unleash Power (ACT UP) is an international, grassroots political group working to end the AIDS pandemic. The group works to improve the lives of people with AIDS through direct action, medical research, treatment and advocacy, and working to change legislation and public policies.
- ACT UP was formed on March 12, 1987, at the Lesbian and Gay Community Services Center in New York City.
- Larry Kramer was asked to speak as part of a rotating speaker series, and his well-attended speech focused on action to fight AIDS.

https://en.wikipedia.org/wiki/ACT_UP

FDA activities...





2020

2019

2018

2017

- COVID-19 Patient resources page Launched
- Final PFDD guidance 1 released
- Muscular Dystrophy Association webinar on COVID-19
- FDA and NORD listening session on COVID-19 impact on rare disease communities

- FDA launched Patients Ask FDA
- PFDD workshop on guidance 4
- Draft PFDD guidance 2 released

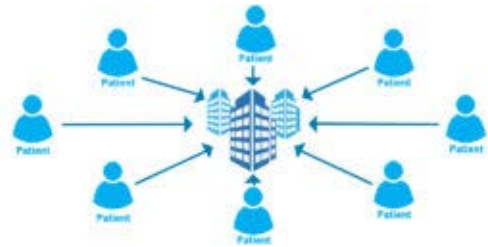
- Memorandum of Understanding with National Organization For Rare Disorders launched the Patient Listening Session pilot program
- Patient Engagement Collaborative launched with Clinical Trials Transformation Initiative
- Center for Devices and Radiological Health Patient & Caregiver Connection program launched public workshops on PFDD guidances and drafts released

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Patient and Public Involvement during the COVID-19 Pandemic

Decentralized Clinical Trial

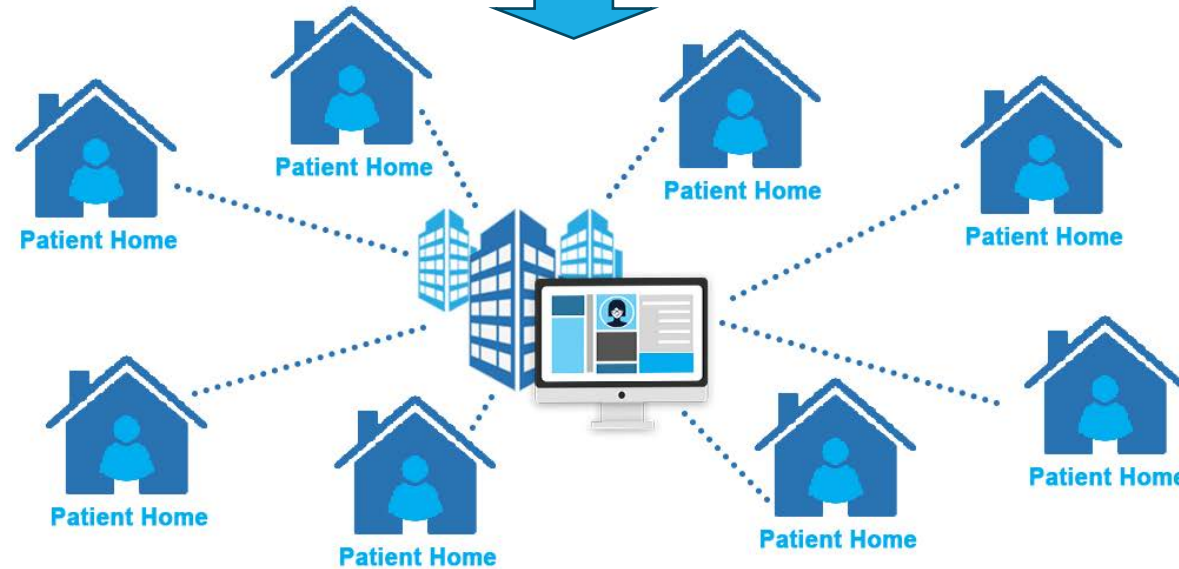
<https://florencehc.com/blog-post/decentralized-clinical-trials-what-the-future-holds/>



Traditional Clinical Trial



Decentralized Clinical Trial



Virtual Clinical Trial



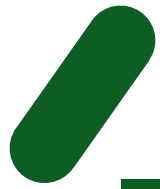
An example to collect PRO data of COVID-19 aftereffects



Prof. Satoshi Kutsuna, Osaka university

<https://prtimes.jp/main/html/rd/p/000000043.000036622.html>





DeTap Trial

Sarraj, A., Seninger, C., Parameswaran, V. *et al.* Pandemic-proof recruitment and engagement in a fully decentralized trial in atrial fibrillation patients (DeTAP). *npj Digit. Med.* 5, 80 (2022). <https://doi.org/10.1038/s41746-022-00622-9>

Article | [Open access](#) | [Published: 28 June 2022](#)

Pandemic-proof recruitment and engagement in a fully decentralized trial in atrial fibrillation patients (DeTAP)

[Ashish Sarraju](#), [Clark Seninger](#), [Vijaya Parameswaran](#), [Christina Petlura](#), [Tamara Bazouzi](#), [Kiranbir Josan](#), [Upinder Grewal](#), [Thomas Viethen](#), [Hardi Mundl](#), [Joachim Luithle](#), [Leonard Basobas](#), [Alexis Touros](#), [Michael J. T. Senior](#), [Koen De Lombaert](#), [Kenneth W. Mahaffey](#), [Mintu P. Turakhia](#) & [Rajesh Dash](#)

npj Digital Medicine 5, Article number: 80 (2022) | [Cite this article](#)

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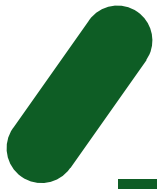
Abstract

The Coronavirus Disease 2019 (COVID-19) pandemic curtailed clinical trial activity. Decentralized clinical trials (DCTs) can expand trial access and reduce exposure risk but their feasibility remains uncertain. We evaluated DCT feasibility for atrial fibrillation (AF) patients on oral anticoagulation (OAC). DeTAP (Decentralized Trial in Afib Patients, NCT04471623) was a 6-month, single-arm, 100% virtual study of 100 AF patients on OAC aged >55 years, recruited traditionally and through social media. Participants enrolled and participated virtually using a mobile application and remote blood pressure (BP) and six-lead electrocardiogram (ECG) sensors. Four engagement-based primary endpoints included changes in pre- versus end-of-study OAC adherence (OACA), and % completion of televisits, surveys, and ECG and BP measurements. Secondary endpoints included survey-based

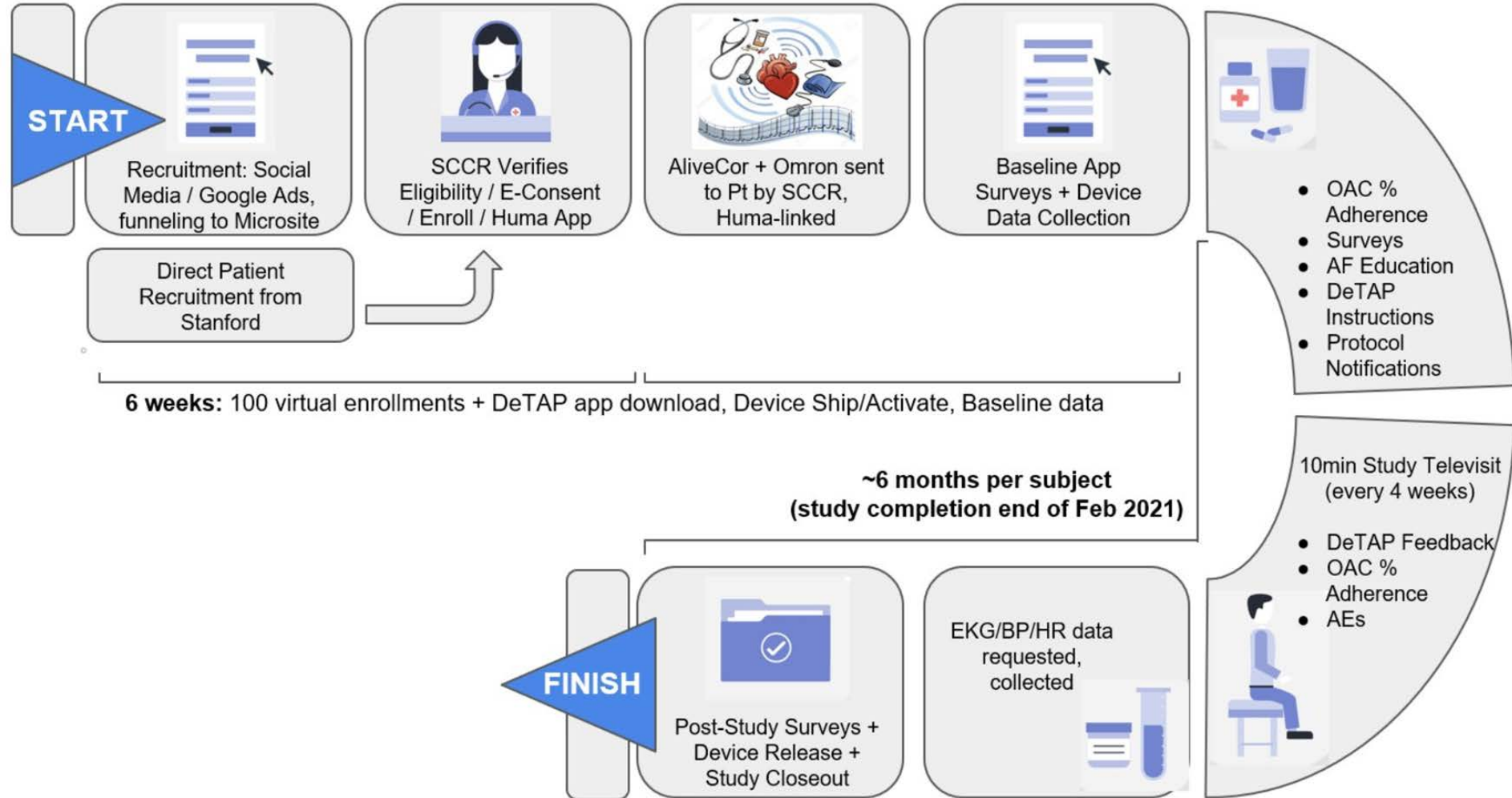
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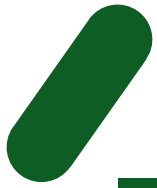
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DeTap trial Design





Limitation

- Our study had certain limitations. The majority of our participants were White and urban dwelling, and nearly 70% of our population had bachelor's degrees or higher levels of education, which limits the generalizability of our findings. Future efforts should develop and validate decentralized protocols in more diverse populations to ensure that the use of digital technologies does not exacerbate existing health inequities. Adapting recruitment strategies to focus on participant diversity as a key trial metric may help address this goal. OAC adherence was fully self-reported and was not validated objectively by study investigators.



EUPATI; European Patient Academy



European Patients' Academy

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Clinical Trial Ambassador, using EUPATI training material (Austria, Japan)

Orientation for representative of Patient Organizations

- 1 | 27- 28 July 2022 – virtual
- Introduction about project overview 2022
 - Introduction about the training contents



Hands-on Training - Where to find Clinical Trials information?

- Oct 2022 – virtual
- Looking back the training and discussion at initial training
 - Training and Demonstrations
 - how to access clinical trial information
 - Discussing any specific future initiatives
 - What you or your patient organization can do based on what you learned

3



Workshop - Wrap up about the Ambassador role

- 4 | Nov 2022 – virtual
- Review of initial training and hands-on training
 - Discussion
 - What you learned and practiced in the Clinical Trial Ambassador project
 - What do they need in addition to planned training?

4



2 Initial Training

- 31 Aug 2022 – virtual
- Looking back discussion about Ambassadors role in 2021
 - Providing initial training
 - Overview on drug development process, Clinical Trials
 - Discussing the needs of access to clinical trial information
 - What information do you (or others in your patient organization) want about clinical trials?
 - Input any specific initiatives for the future





Localization; JI4PE A~E course

<p>01 </p> <p>PE Expert</p> <p>体系的な人材育成(PEエキスパート学習コース)</p> <p>Read more ></p>	<p>02 </p> <p>Clinical Trial</p> <p>患者市民参画推進のための職場トレーニング</p> <p>Read more ></p>	<p>03 </p> <p>for Kids</p> <p>楽しく学べる子供たちのための社会学習コース</p> <p>Read more ></p>	<p>04 </p> <p>Consulting</p> <p>オンデマンドの調査研究コンサルティング</p> <p>Read more ></p>
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体系的な人材育成(PEエキスパート学習コース)

当法人では、患者・市民と企業・アカデミアが医薬品の開発から承認後の処方に至るまでのプロセスについて共通の理解を持つために、体系的な学習コースを提供します。

① PEエキスパート学習コース各カテゴリーの概要はこちら

各コース概要をご理解の上、参加を希望される場合は、下記より参加申請をお願いいたします。

- ② A.患者・市民のための人材育成コース(イントロコース)：主に患者・市民向
- ③ B.組織リーダー育成コース：主に患者・市民向
- ④ C.開発基礎知識コース：業界・アカデミア、その他向
- ⑤ D.開発専門家コース(SMD認定)：業界・アカデミア向
- ⑥ E.倫理審査委員育成コース(Ethics)：主に患者・市民向



JI4PE each educational course
 Human Resource Development for Patient Citizens (A), for Patient Organization Leaders (B)
 Ethics Committee Member Training (E)
 is mainly for patients and patient supporters.
 Currently, people having patient background are challenging course C (Pharmaceutical Medicine Training)

Co-creation new therapies with Patient and Public

I received a very detailed lecture on the mechanism of clinical trials and related knowledge. I hope that more people will have a good understanding of clinical trials.



I thought it was an unprecedented activity. I am glad that the project was an activity that involved multiple stakeholders and allowed for interactive discussions with patients and companies!

We hope that the success of our clinical trial ambassadors will increase the number of participants in clinical trials and bring better drugs to the market faster.

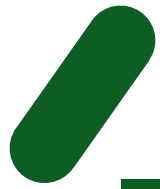


I hope that by informing people who don't know about the clinical trial, I can dispel their fears.

Patient Engagement; What's next?



- ❑ It includes people across organizations who have expertise in supporting the quality of life of patients and citizens.
- ❑ The purpose of the activities is to be meaningful to all involved.
- ❑ It provides a venue and resources for mutual learning, rather than simply making a request or offering support to someone else involved.
- ❑ It seeks to understand, propose, and realize together in order to achieve the desired results for all involved.
- ❑ They plan so that many people can take advantage of the results.



Special Present for you!

- Widmung, Myrthen, Schumann

You my soul, you my heart,
you my bliss, O you my pain,
you my world in which I live,
my heaven, thou into which I float,
O thou my grave, into which
I eternally gave my sorrow!
You are rest, you are peace,
thou art my heaven.
That you love me makes me worthy,
Your gaze has transfigured me before me,
You lift me lovingly above myself,
my good spirit, my better self!



Tomoaki Yokoyama,
composer, pianist