

Personalized Health Solutions

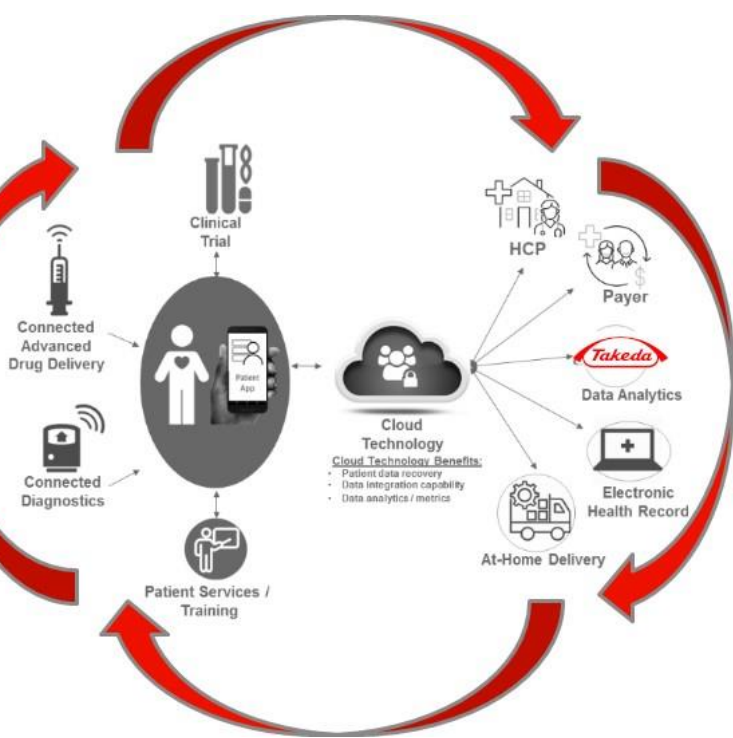
Device Case Study: myPKFiT for ADVATE / ADYNOVATE

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Medical Devices Center of Excellences, R&D, Shire HGT, Inc., Lexington, MA, a Takeda company

Introduction: Connected Ecosystem Vision

A Connected eHealth Ecosystem that encompasses the drug, drug delivery, diagnostics, and connectivity and services can enhance the user experience and drive value:



Example Benefits:

- **Patient Empowerment** - Patients are able to “own treatment” by tracking treatment therapy, owning their data, and sharing data with their healthcare provider.
- **Patient Education** - Patients are able to learn about disease state management and treatment.
- **Drive Adherence** – Patient app tools and education leveraging dosing data (e.g. behavior modification, gamification) can be used to motivate and encourage patient adherence to their HCP’s treatment plan.
- **Generate Healthcare Provider Insights** – HCPs are better informed of their patient’s adherence between office visits, allowing care teams to better track, manage, and adjust patient care plans.
- **Product Feedback Loop** – Takeda learns how patients and HCPs use the connected devices and services in the real world (e.g. which features are used/not used, frequency of use, etc.), which will inform future product features and design improvements.

Case Study: Personalized Health Solution (myPKFiT)

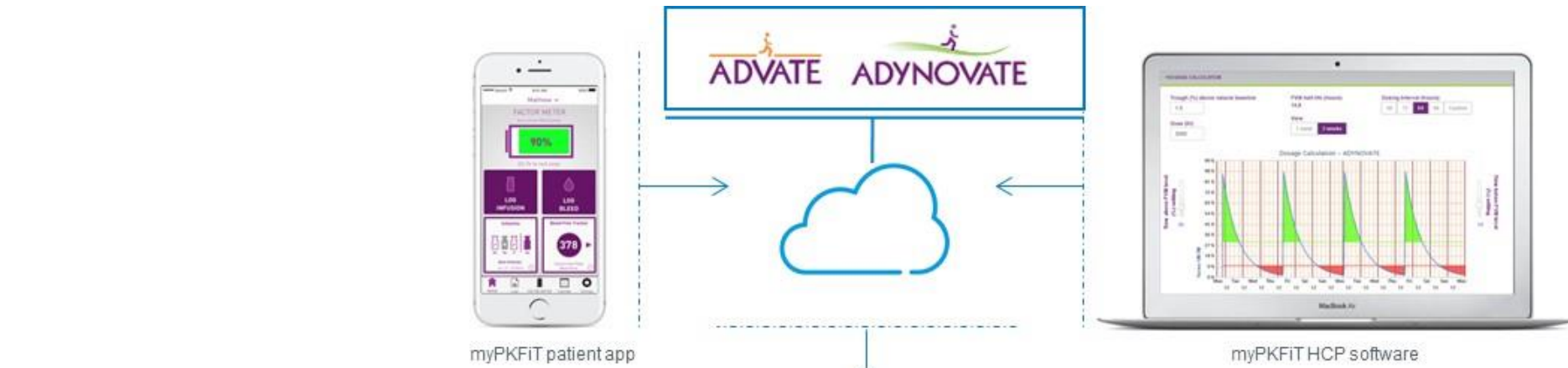
Prophylaxis must be personalized to achieve better outcomes... because everyone is unique. Pharmacokinetics is a critical element of personalization... as interpatient variability creates uncertainty in outcomes.

Unmet Medical Need

- Physicians do not have a way to create a personalized dosing regimen for every patient
- Patients do not have an easy way to keep track of their infusion schedule and bleed activity and share with their care team
- Patients do not have insight to their current FVIII levels

Value Proposition and Differentiation

- Personalized dosing per patient PK curve
- PK dosing based on only 2 blood draws vs 11 previously
- Patients can log their infusion and bleed infusion and easily share with their care team
- Patients can keep track of their FVIII levels in real time following prophylaxis infusions



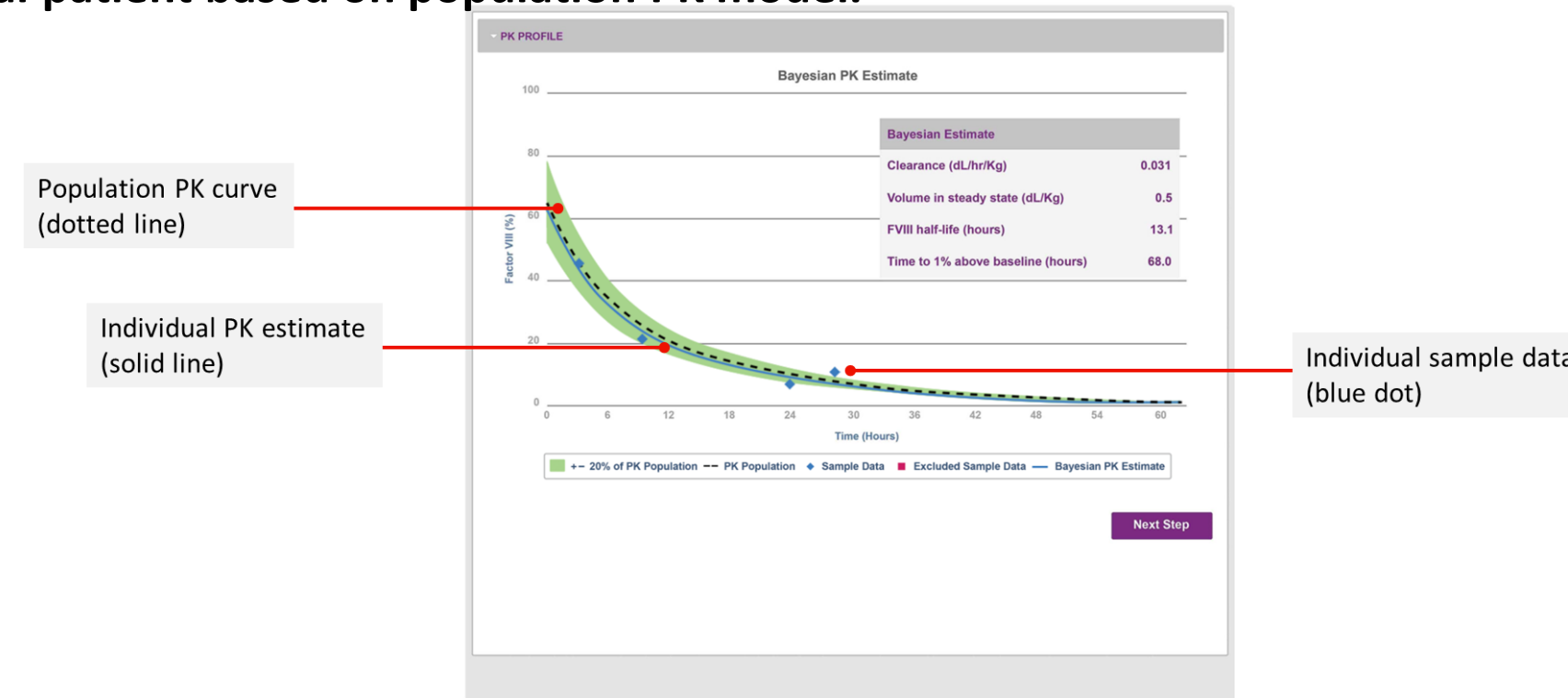
myPKFiT Patient Application (ADYNOVATE / ADVATE)
The myPKFiT Patient APP (cloud) takes the personalized dosing recommendation from the myPKFiT HCP and allows the patient to manage an eDiary (e.g., bleeds and infusions log) and to track factor coverage through the “factor meter”.

myPKFiT HCP v3.0 (ADYNOVATE / ADVATE):
The HCP device is a standalone web-based software medical device intended to be used by healthcare professionals (HCPs) who are providing hemophilia care and provides dosing recommendations.

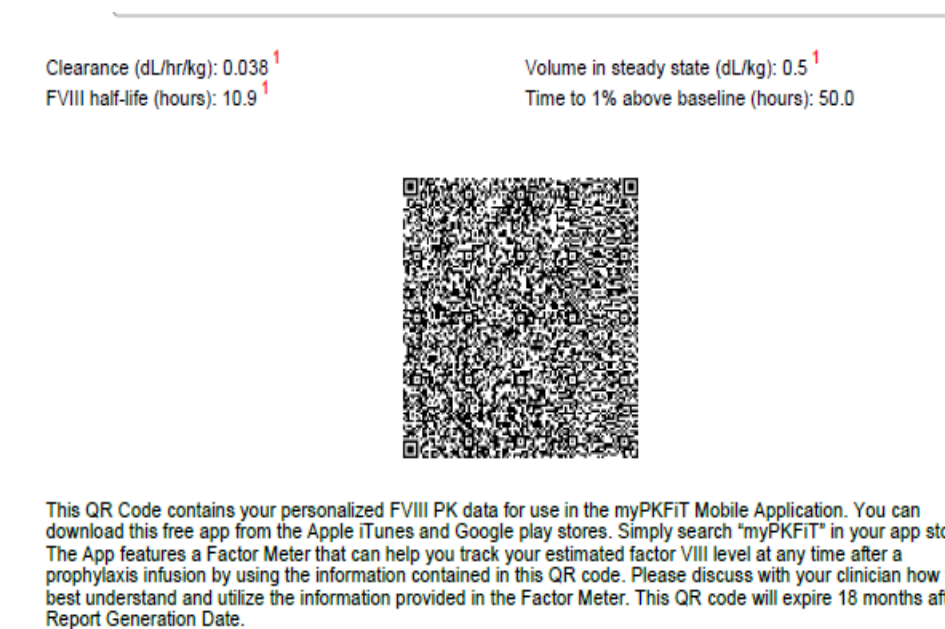
Solution: myPKFiT: Practical and reliable estimate of individual personalized prophylaxis (PK) regimen

The software output may be used to guide decisions on appropriate dosing and infusion intervals to maintain FVIII activity levels at or above a user specified minimum FVIII activity level between 1% - 3% above natural baseline for an individual patient in accordance with the FDA-approved dosing regimens provided in the ADVATE Prescribing Information (PI).

myPKFiT uses a Bayesian calculation to determine the estimated PK parameters for an individual patient based on population PK model.



The personalized assessment information is saved to a PDF for the patient. The PDF contains a QR code for use in the myPKFiT Mobile Application. The patient gives access to the Healthcare Provider using mobile app. The HCP will then have access to Data Sharing for all consenting patients, patient report, and mobile app usage results.



myPKFiT allows you to model personalized dosing regimens for your patient based on previously estimated individual PK parameters. Adjustments can be made to visualize target trough above baseline, dosing intervals and assess the dosing schedule in a table format.



Looking Forward: Personalization Health Solutions

The Connected Ecosystem is foundational to Personalized Health Solutions. Increasingly, connected and software devices will utilize data to:

- Gain insights
- Improve our products
- Provide seamless data share within the care network
- Improve research
- Drive decisions
- Demonstrate outcomes

Consideration: Emerging Compliance Environment

Device classification is dependent on geography of WHERE the device is used and HOW the device is used. At summary level, device functionality includes although is not limited to:

- ✓ Software performs an action on data
- ✓ Software performs a measuring function
- ✓ Software data is used by Health Care Professional to make decisions



- Examples:
- Unique County Hosting requirements: France (ASIP – Santé); Russia, China
 - Unique and changing qualifications: QMS qualifications include: ISO13485, IEC 62304, ISO14971, MDSAP, MDR, etc.
- Examples:
- Product Feature Expansion / Geo-Graphic Expansion: As connected platforms are used and features expanded (including drug product references), then the intended use of devices on market may change and may require regulatory updates; or, device classification may be required.

Technical Disclosures

- The myPKFiT Device has been developed by internal cross-functional Takeda device teams (e.g., Medical Devices CoE, R&D; Global Product Teams Commercial; Global Medical Affairs; Global Device Regulatory; Global Device Quality Management; Legal; Data Privacy; etc.) and funded internally by Takeda. myPKFiT has several international patents pending. The myPKFiT personalization is available only for the Takeda products ADVATE and ADYNOVATE. myPKFiT for ADVATE and myPKFiT for ADYNOVATE are commercially launched devices following device design controls in compliance with ISO:13485/MDSAP guidance. The myPKFiT device label is noted as being manufactured by “Shire plc, a wholly owned subsidiary of Takeda”.
- The screen shots are taken with mock patient data from a demonstration (non-production) environment although reflective of the production myPKFiT version. No personal health data was used to create this poster.
- The future of personalized health solutions are the opinions of the Takeda Medical Devices CoE.