Datacubed Health

A CLOSER LOOK AT DATACUBED HEALTH LINKT

WHITE PAPER

INTRODUCTION

Patients are vital to the success of any clinical trial. Yet many trials struggle to keep patients engaged for the duration of the study. Sponsors often treat patients as subjects, not as partners, with little or no interaction between study visits. Low engagement leads to poor patient compliance, high rates of dropout, cost overruns, and trial delays. Ultimately, it slows time to market. While clinical trials have lagged in creating strong engagement, other industries keep raising the bar on customer experience. Their innovations have shown that one of the most powerful engagement tools is the customer's own smart phone.

Datacubed Health has developed a sophisticated solution that brings the best of customer experience and engagement to the realm of clinical trials. That solution includes Linkt, Datacubed Health's mobile app for patient engagement. Linkt offers the personalization, motivational design, and intuitive ease of use customers expect. But does it also deliver the reliability, security, and data management capabilities that a clinical trial demands?

This white paper explains what differentiates the Linkt app and the mobile infrastructure behind it.

IS THERE REALLY AN APP FOR THAT?

Using patients' own smartphones, the Linkt app provides a tool for keeping patients informed and engaged. It makes it easy for patients to enter their own health information – and for a trial sponsor to be alerted to possible visits to a clinic, hospital, or other medical facility. Linkt is not only simple to use; it's also fun.

In exploring the app, concerns from sponsors and CROs often cluster around these four questions:

1. Will older patients use Linkt?

It's understandable to assume that patients who have grown up with technology would be most likely to embrace the app. In reality, *all* age groups do well with the interactive elements of the solution. Surprisingly, participants who are 55 years and older are particularly interested. In fact, engagement with Linkt's Avatar Store within the app increases with participant age and is highest among those ages 55 and up.

2. What if a patient doesn't have a reliable Internet connection?

Linkt is designed so that patients do not need an Internet connection. Patients can complete tasks and instruments online or offline, and passive data is collected with or without a connection. When patients are again connected (for example, during a study visit), the app sends the data to the Datacubed Health server. There is no loss of data and no need for patients to repeat instruments.

3. Is the app too gamified?

Datacubed Health has intentionally designed Linkt to be engaging and motivational so that patients are more likely to participate in the study for the long term. Gamification,

data visualizations, and rich interactions are layered with behavioral reinforcements. These features help link a patient's sense of self to their participation in the study. Linkt also incorporates short-term and long-term motivators and custom rewards that help achieve retention and compliance rates of more than 90 percent.

4. Does the app track patients' locations?

In a word, no. *Geotracking* enables the exact tracking of a person through data on a smartphone. The Linkt app does not use geotracking. It uses *geofencing*, which offers high privacy as it records only breaches of "fences" established around medical facilities. In other words, there is no insight into a patient's location unless and until that patient enters a medical clinic or hospital, indicating a potential adverse event.

The balance of this paper provides technical detail to explain the strengths of Datacubed Health's approach and how these set Linkt apart from similar mobile apps.

FOUNDATION OF STRENGTH AND RESILIENCE

Linkt's differentiation starts with how it is developed. Datacubed Health follows industry-leading mobile development practices for both the Android and iOS environments.

Android

Google's Modern Android Development (MAD) Score reflects a blueprint for building better Android apps. The Linkt app performs consistently well on key indices, including level of adoption of Kotlin, Google's modern, expressive language for app development. Linkt's high Jetpack score reflects backward compatibility with older versions of the app and the ability to support Android devices of virtually any age. More specifically, Linkt supports Android 6.0 (Marshmallow) onwards, covering eight different versions of the operating system. Datacubed Health also has optimized download size (see Figure 1).

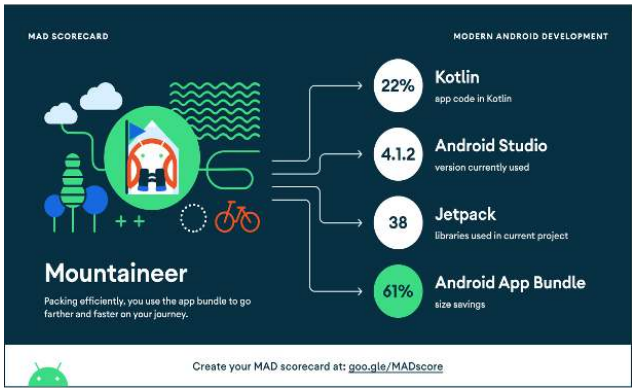

Figure 1
Datacubed Health has optimized Linkt to enable a smaller download size.
While most Android apps eke out 20%-25% size savings using the Android App Bundle, Datacubed Health has compressed Linkt's download size by 61%.

iOS

When programming for iOS, Datacubed Health uses XCode 12.4, Swift 4.2, and reactive programming methodology, an approach that produces code that is more maintainable, scalable, extensible, and reliable.

As with Android, Linkt on iOS is designed to evolve over long periods of time without losing backward compatibility. For example, a clinical trial that runs for five or even 10 years can be continuously supported. The app can still support the five-year-old data while incorporating newer enhancements—and it can do all of that with reliable performance.

On iOS devices, the Linkt app uses the Realm library for its speed and security capabilities. Realm can handle over 7x more queries per second than other databases running

KEY TAKEAWAY: This development foundation makes Linkt universally accessible. The app performs reliably whether a patient logs in from a 10-year-old Android device or the latest iPhone. Just as important, it can support clinical trials spanning multiple years without compromising data management or access to the latest app features.

on iOS. Realm also offers industry-leading security of data when in transit or stored in the app.

TEST-DRIVEN DEVELOPMENT

Traditional software quality assurance (SQA) performs functional tests to ensure that a system meets requirements at an acceptable level. SQA is a process that occurs after the software is created. In addition to SQA, Datacubed Health has embedded testing into the actual development process.

Our developers perform tests at the unit level—the smallest piece of code that can be logically isolated in a system. Unit testing, which is an essential part of Test Driven Development (TDD), helps surface issues at the software construction stage. That, in turn, prevents bugs from creeping into subsequent development stages, which saves time and money.

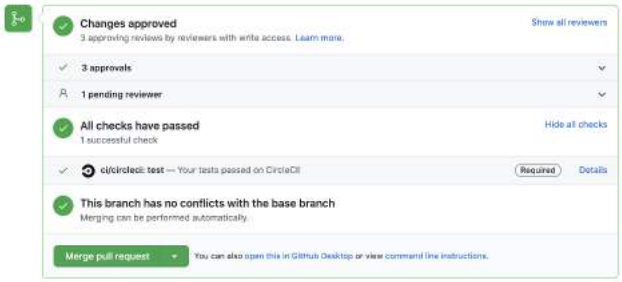

Figure 2
Datacubed Health's infrastructure automatically runs unit tests on all changes to code. This is an example of a resulting report, which shows details of exactly which test is failing and why.

With TDD, developers can identify and correct bugs easily and quickly by writing a few lines of testing code. This not only produces a better first-round app; it also makes the software easy to maintain over time. In addition, it facilitates changes and simplifies integration—enabling Datacubed Health to refactor with confidence, an inevitability for long-running studies.

Perhaps most importantly, unit testing covers tests for cyclomatically complex pieces of software (that is, a larger number of pathways through a portion of code). This level of testing is difficult to cover with traditional SQA test cases. Unit testing can validate:

- Calculations involving date and time, guaranteeing consistent data quality anywhere and anytime,
- Code involving complex mathematical calculations, guaranteeing precision of data, and
- Variable output based on the input provided, guaranteeing quality, correctness, and consistency of data.

KEY TAKEAWAY: For Datacubed Health, testing and quality are not afterthoughts. We perform unit testing as part of the development process—dramatically improving quality and reducing the likelihood of bugs. It also makes it easier to add new features and scale the app with absolute confidence.

AUTOMATED RELEASES ON ANDROID AND IOS

Manually pushing releases on both Android and iOS is time consuming and prone to errors. Datacubed Health has automated the release cycle on both Android and iOS.

By removing the risk of human error, this approach makes the process repeatable, faster and more dependable. Datacubed Health customers, as well as patients using Linkt, benefit from monthly releases that further enhance the app.

KEY TAKEAWAY: Datacubed Health has automated releases so new features reach users more quickly and reliably.

ROBUST SECURITY MEASURES

Datacubed Health secures our mobile infrastructure and Linkt app with industry-leading practices. For example, by applying double encryption to participant data, we ensure data is doubly secure while in transit. We rotate encryption keys every 24 hours, limiting any possible impacts of a

security incident to a one-day window. We run all network operations through *https* for another layer of security and trust—and our access control policies offer protection against unauthorized users.

Linkt also has mechanisms to protect patient-generated data that may be temporarily stored in the app—for example, survey responses or geofencing triggers that occur when the app is offline. The app attempts to send participant data every few minutes in the background even if the app is not running, and it requires no actions of the patient. In these ways, it guarantees no loss of data. And once data is successfully sent to the server, Linkt deletes the collected data from the patient's mobile device. This ensures that data does not live on the application for an extended period.

KEY TAKEAWAY: Linkt has mechanisms for safeguarding patient data while on a mobile device and for ensuring that data is sent to the server quickly and with no action required of the patient.

VERSION CONTROL

Datacubed Health uses module versioning and schema definitions to ensure that Linkt offers backward and forward compatibility—critical for any study but especially for trials running over many years.

Within our mobile infrastructure we track versions and create documentation as follows:

- **Data versioning**—applicable to *all* collected data—guarantees consistency for long-term studies.
- **Database versioning** for mobile databases ensures no loss of data between application updates.
- **Release versioning** and tagging ensure a trail of the exact code that went in every release.

ALERT MECHANISMS

Though a rare occurrence, when there is an issue with the app, Datacubed Health has a robust process for identifying and responding—typically before patients or trial sponsors would even notice.

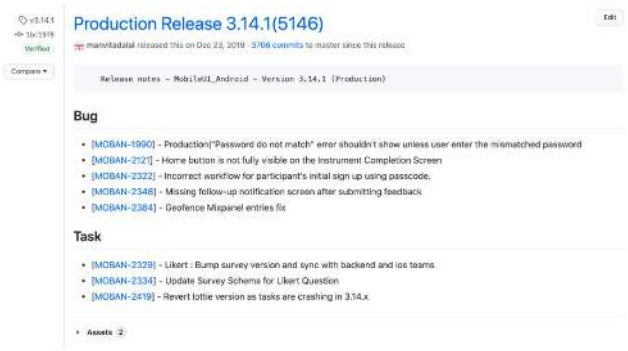

Figure 3
Datacubed Health captures details on every change made to the Linkt app.

KEY TAKEAWAY: Our mobile infrastructure maintains full version control and can accurately interpret data no matter when (or on what device) it was collected.

CONCLUSION

For patients of all ages, the Linkt app is simple, easy, and intuitive to use—providing a powerful way for trial sponsors to interact with patients throughout a study. Behind the scenes, the app is powered by a robust mobile infrastructure and backed by disciplined development and maintenance processes. The result is a one-of-a-kind solution for better patient engagement and, ultimately, more successful trials.

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