

The Precision Engine Company

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FastFinder:  
a secure and  
reliable platform.

VELSERV

## FastFinder: a secure and reliable platform.

### Importance of security in molecular diagnostics

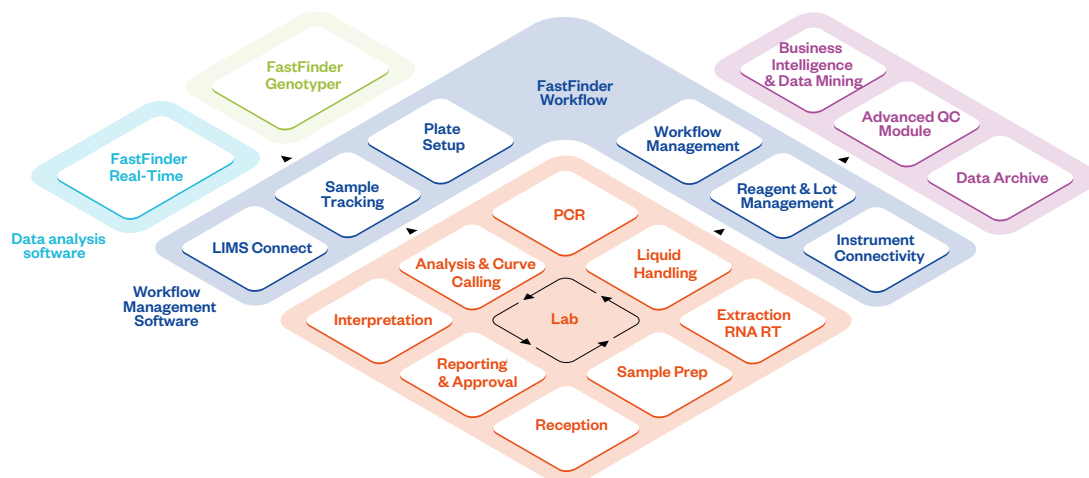
In a molecular testing setting, labs are dealing with confidential research or healthcare-related data. Ensuring the security of data is important in both research and clinical environments, as it involves safeguarding research findings, intellectual property, patient-sensitive information, consent, and adhering to the specific regulations governing Personal Health Information.

#### FastFinder is built from the ground up for clinical use.

- A sound and proven security model with multiple layers of security
- Regular audits and security checks
- Implementation of industry guidelines and best practices
- Partnership with a best-of-class infrastructure provider
- Audit trails and change validation



For a more detailed discussion on Velsera's secure platform, please consult the FastFinder hosted solutions white paper.



## Multiple layers of security

The FastFinder software maintains three layers of protection, ensuring industry-grade security across the platform. All communication between the different modules of the FastFinder system is encrypted through SSL<sup>1</sup> as a security layer, combined with the OAuth2 protocol<sup>2</sup> as an authentication layer. On top of those, both the end-user facing applications and the centralized administration module provide an extra authorization layer, which allows specific user actions to be assigned to specific users through user roles.

Additionally, all data storage has been configured to be encrypted at rest, thanks to features provided by Microsoft. This encryption is applicable for file storage, as well as the underlying data storage of databases.

## Externally audited procedures and infrastructure

FastFinder has documented procedures in place that govern its development and production infrastructure, hosting and deployment process, security management including user access and entitlement management, intrusion detection, and more. FastFinder regularly tasks an independent, external party to perform a full set of manual & automated penetration tests on the FastFinder software solution.

## Implementing relevant security guidelines

Specific rules, guidelines and best practices apply to PHI (Personal Health Information). FastFinder ensures that its platform supports compliance with guidelines such as GDPR<sup>3</sup>, APP<sup>4</sup>, HIPAA<sup>5</sup>, and general industry best practices. Moreover, to ensure the highest security standards, CAP<sup>6</sup>/CLIA<sup>7</sup> security guidelines are also implemented.

1. Secure Socket Layer
2. OAuth 2.0 is the industry-standard protocol for authorization
3. The General Data Protection Regulation (GDPR) is a European piece of legislation which covers personal information and how consumers and businesses interact with it
4. The Australian Privacy Principles (APP) are part of the Privacy Act law that governs privacy of data in Australia
5. The Health Insurance Portability And Accountability Act (HIPAA) is a USA piece of legislation which provides security provisions and data privacy, in order to keep patients' medical information safe
6. College of American Pathologists
7. The Clinical Laboratory Improvement Amendments (CLIA) are United States federal regulatory standards that apply to all clinical laboratory testing performed on humans in the United States, except clinical trials and basic research

## Top notch hosting professional partner

In selecting a partner for its hosted solutions, Velsera has chosen Microsoft Azure, a PaaS (Platform as a Service) provider that's highly secure by design, and that has a track record of providing services to software companies that manage and process PHI. For example, Microsoft has a long history of developing highly secure and safe software for enterprises and the medical device industry that allows customers to be HIPAA compliant. For a full list of their compliance & quality efforts, please refer to the Microsoft Azure Center website.

## Audit trails, change documentation, and robust authentication and authorisation

The FastFinder platform is built with a user-centric authentication and authorisation model, which enables features like two-step validation (where a result by 1 operator has to be confirmed by a second scientist) and audit trails. For example, whenever a user overrides an assay result in the software through the "Resolve" function, she/he is required to enter a rationale, which is stored in the audit trail for future reference.

CFR 21 Part 11, regulations established by the United States Food and Drug Administration, describes the controls it requires to be in place to make sure electronic data is subject to signed document audit trails, record keeping, and access controls.



# FastFinder: a secure and reliable platform.

- A powerful platform built from the ground up with quality and regulatory compliance in mind
- A team of experienced experts to help with the software portion of IVD submissions to regulatory instances
- Supports your lab or diagnostic kit provider compliance need

