

Leveraging the precisionFDA bioinformatics platform to support developers



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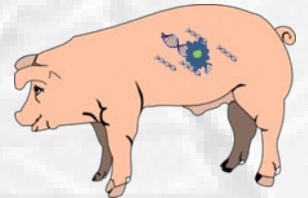
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Disclaimer: *The information in this presentation represents the opinions of the speaker and does not necessarily represent FDA's position or policy.*

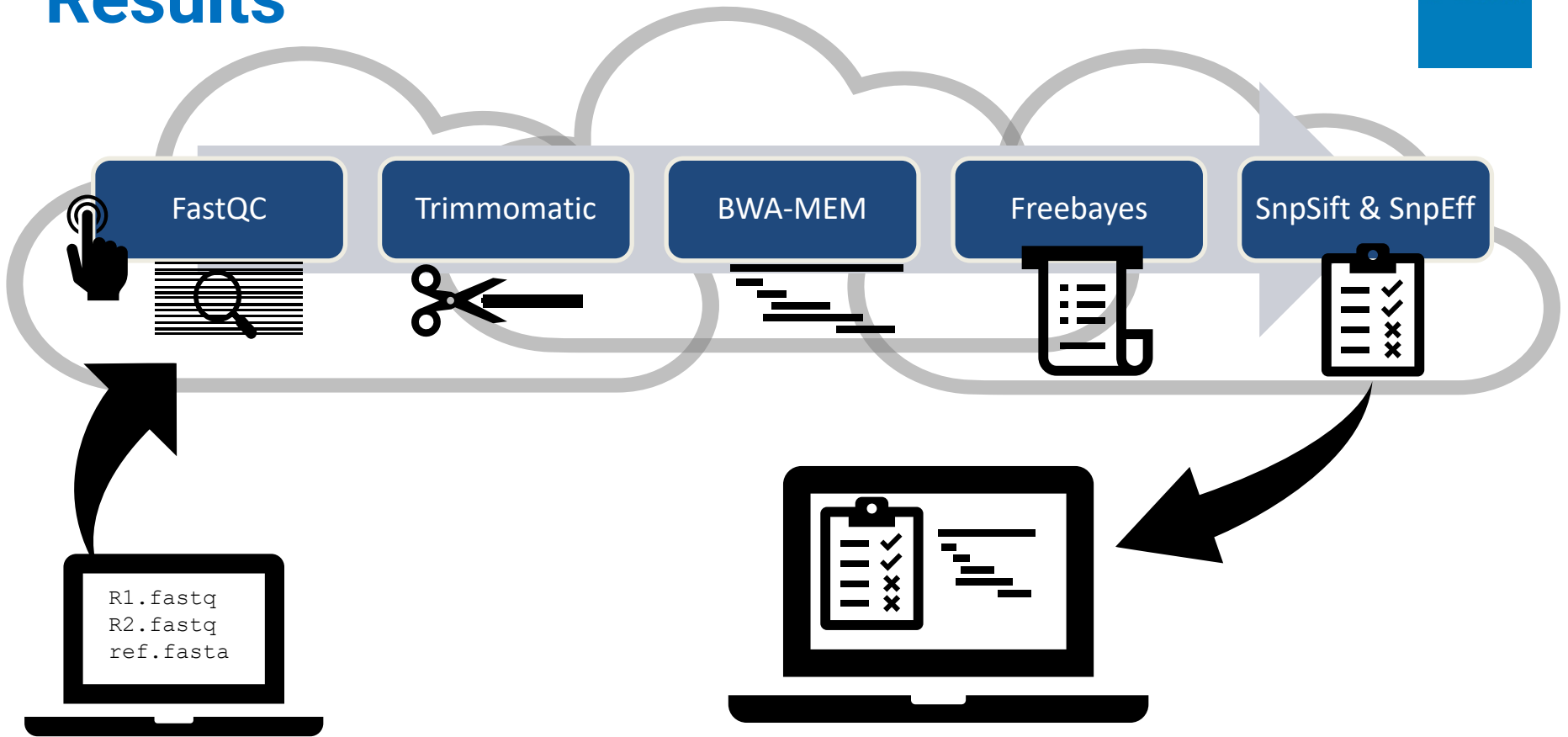
Introduction

CVM's *Veterinary Innovation Program (VIP)*

- Products:
 - Intentional genomic alterations (**IGAs**) in animals
 - Animal cells, tissues, and cell- or tissue-based products
- Benefits:
 1. Intensive review team, senior management, and developer interaction
 - 2. Hands-on assistance**
 3. Review process benefits
- Aim: use precisionFDA to provide next generation sequencing (NGS) data analysis **assistance** to developers of **IGA** products, to:
 1. Confirm intended genomic alteration(s)
 2. Screen for unintended genomic alterations

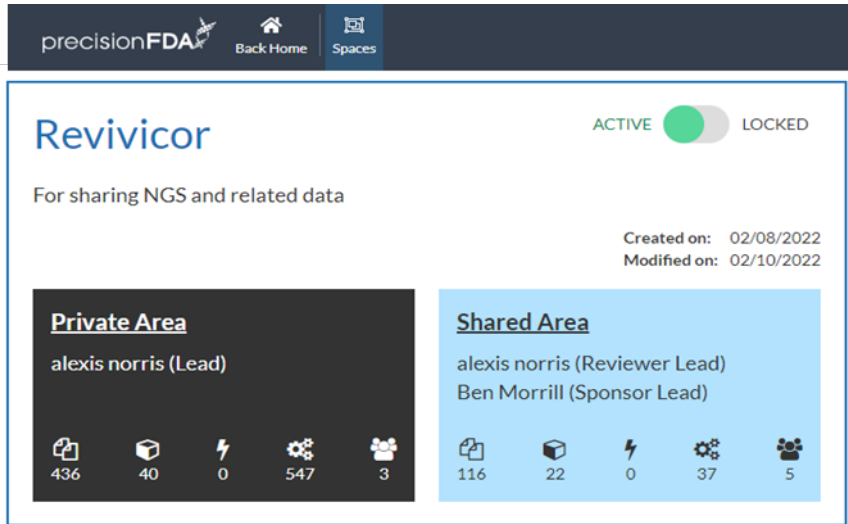


Results



Conclusion

Animal biotechnology developers can now leverage our suite of Apps through precisionFDA Review Spaces to increase the quality and speed of NGS submissions.



The screenshot shows the precisionFDA interface for a Review Space named "Revivicor". At the top, there is a navigation bar with "precisionFDA", "Back Home", and "Spaces" buttons. The "Revivicor" space is currently "ACTIVE", indicated by a green toggle switch. Below the name, it states "For sharing NGS and related data". The creation and modification dates are "Created on: 02/08/2022" and "Modified on: 02/10/2022". The interface is divided into two main sections: "Private Area" and "Shared Area".

Area	Lead	Documents	Submissions	Alerts	Settings	Users
Private Area	alexis norris (Lead)	436	40	0	547	3
Shared Area	alexis norris (Reviewer Lead) Ben Morrill (Sponsor Lead)	116	22	0	37	5

precisionFDA “Review Space”

1. Private area for reviewer(s)
2. Private area for developer
3. Shared area enables secure sharing and analysis of data, as well as ensuring data provenance

Thank you!



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