



## AI Tools & SW Validation

**Presented by: Yael Nuss**  
**February 2025**





## Experience

- CSV / SW Validation
- Twenty years experience in Life science industry

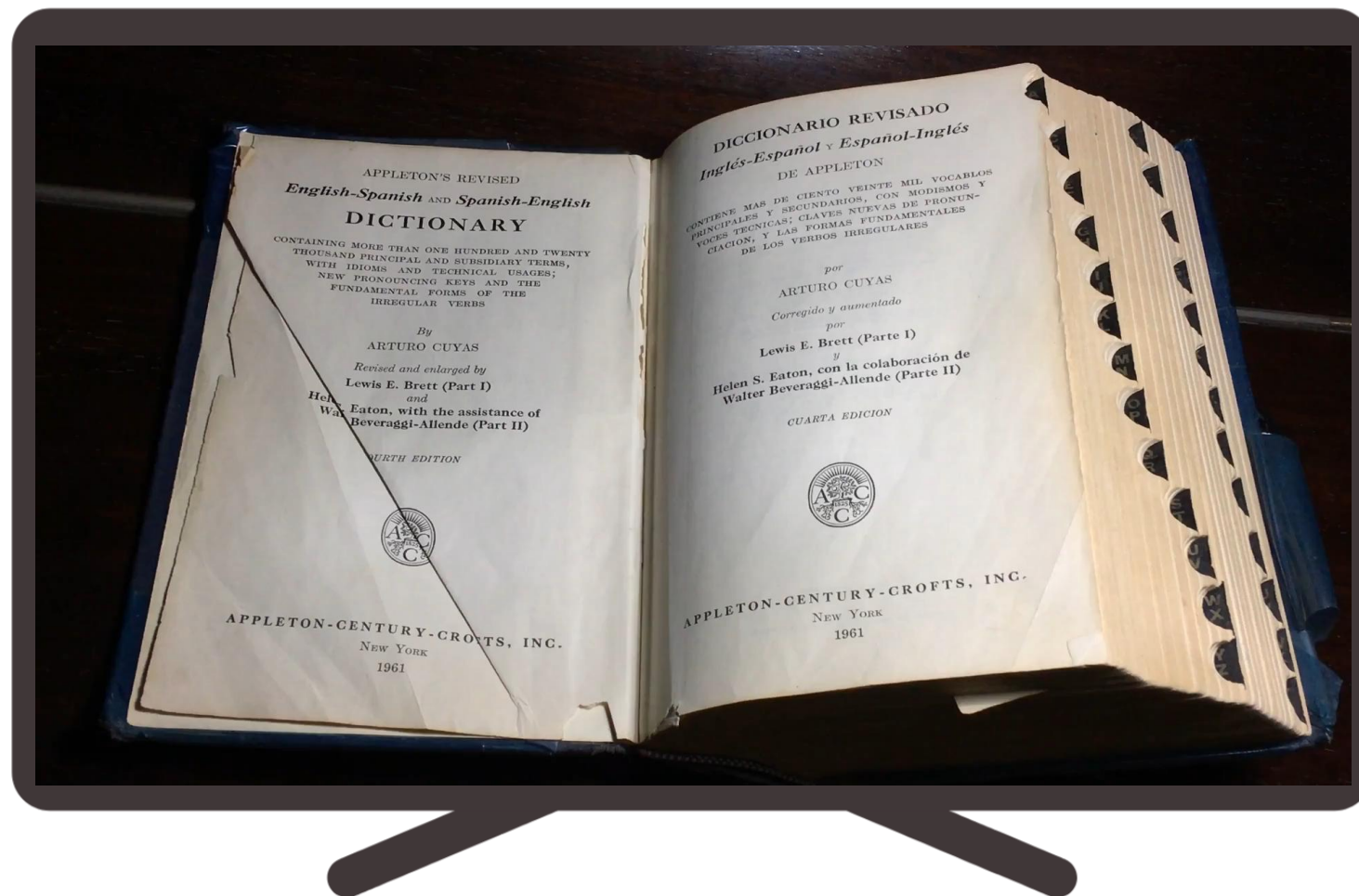
## About R.S NESS Group

The company provides an umbrella of services to the Life science companies (Medical Device, Pharmaceutical, Biotechnological and Medical Cannabis) during their different lifecycle stages incorporating end-to-end project activities while adhering to the regulatory requirements.





# Definitions







# AI

Set of technologies that enable computers to perform a variety of advanced functions.





# Software Validation

The process of evaluating software during or at the end of the development process to determine whether it satisfies specified requirements





## CSV (Computerized System Validation)

The process of evaluating a computerized system (such as ERP or CRM) to determine whether it satisfies specified requirements





## SaMD (Software as Medical Device)

Software intended to be used for medical purposes without being part of a hardware medical device.





## Regulatory Compliance





# AI

ISO/IEC 22989 - Artificial intelligence concepts and terminology

ISO/IEC 42001:2023 - Artificial intelligence — Management system

ISO/IEC 23894:2023 - Artificial intelligence — Guidance on risk management

ISO/IEC 23053:2022 - Framework for Artificial Intelligence (AI) Systems  
Using Machine Learning (ML)



# AI

ISO/IEC 25059:2023 - Systems and software Quality Requirements and Evaluation for AI, from design to deployment and maintenance

FDA's guidance –

Artificial Intelligence and Machine Learning in Software as a Medical Device



## Software Validation

ISO/IEC 62304:2016 - Medical device software – software lifecycle processes

ISO/IEC 90003:2004 - Software engineering — Guidelines for the application of ISO 9001:2000 to computer software

FDA's Premarket Submissions for Device Software Functions



## SaMD

IEC 82304-1: 2016: General requirements for product safety

ISO 14971: 2019: Medical devices — Application of risk management to medical devices

ISO 27799: 2016: Health informatics — Information security management in health using ISO/IEC 27002

FDA guidance on AI/ML in Software as a Medical Device (SaMD)





# Cyber Security

ISO/IEC 27001: 2022 – Cyber security

FDA - Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions







# Cyber security





## פרטים אישיים ומידע רפואי רגיש של עשרות אלפי ישראלים היו זמינים ברשת

קפטן אינטרנט

צילומי רנטגן, תוצאות פענוח ועוד מסמכים של מכוני דימות שונים היו זמינים לכל, בשימוש בדפדפן בלבד ■ "ניהול גישה כה לקוי, שמוביל לחשיפה של עשרות אלפי צילומי רפואיים רגישים לצד מכתבים רפואיים, הוא לא דבר שרואים כל יום", אומר אחד הנפגעים, יועץ אבטחת מידע במקצועו ■ לאחר פריית TheMarker הגישה לאתר נחסמה

## מאות אלפי ישראלים בסכנה: גם הפרטים האישיים שלכם דלפו?

האתר jane.co.il, המשמש לממכר קנאביס רפואי, איפשר גישה בלתי מוגבלת למסמכים אישיים של לקוחותיו, כולל רישיונות להחזקת חומר מסוכן, מרשמים רפואיים ותעודות זהות

## פרצת אבטחה: מידע אישי של מטופלים דלף ממערכות מד"א

דו"חות רפואיים, מספרי תעודות זהות ומספרי כרטיסי אשראי של מטופלים דלפו, אך הארגון לא טרח ליידע את הרשות להגנת הפרטיות, כנדרש בחוק. כמו כן לא דיווחו לה על פרצת אבטחה חמורה באפליקציית ניהול המחלקות





## Top 5 most targeted industries:

1. Insurance
2. Finance
3. Healthcare
4. Law
5. Transportation

Credit: [Must-know phishing statistics for 2025](#) (egress, Dec 2024)



# Cybersecurity AI Tools

Credit:

[7 Best AI Cybersecurity Tools for Your Company](#)

[Top 10: AI Tools for Enhancing Cybersecurity | Cyber Magazine](#)

[6 Types of Best AI Security Tools for 2025 | Strapi](#)

[Top 10 list of AI Tools For Cybersecurity](#)



## Darktrace

Good AI tool for cybersecurity that helps in identifying any ongoing threat.





# Darktrace

## Features

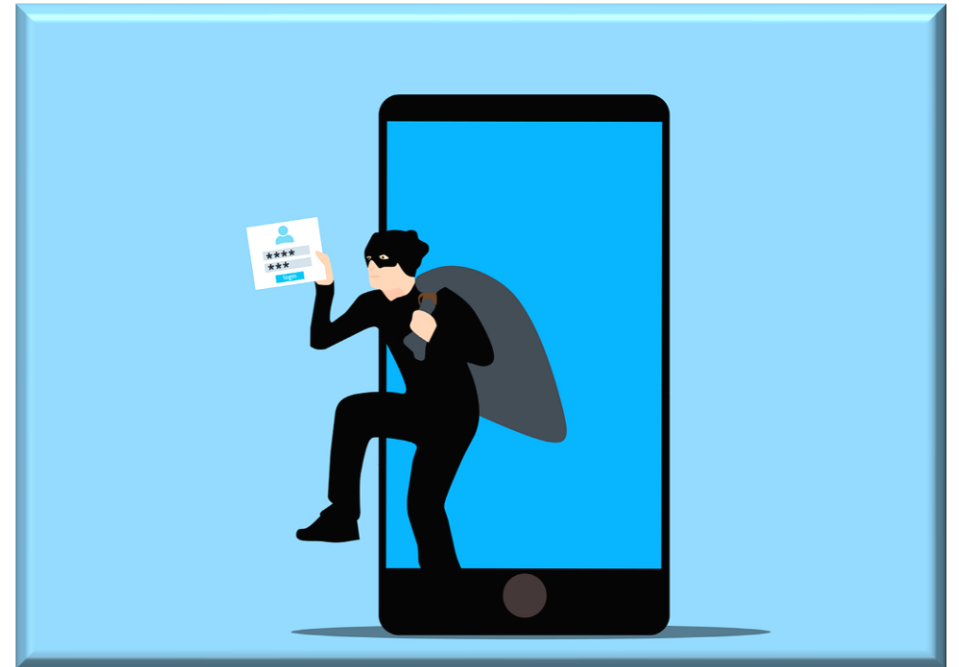
- Easily analyses and adapts to any type of threat.
- It has a self-learning approach towards the systems.





## Cylance

AI tool for cybersecurity that highly focuses on endpoint security solutions.







# Cylance

## Feature

Preventing any type of threat before they become effective.





# SW Validation Execution

## AI Model's Accuracy

Accuracy



## Evaluate Response Time





# Penetration testing





# Privacy Testing







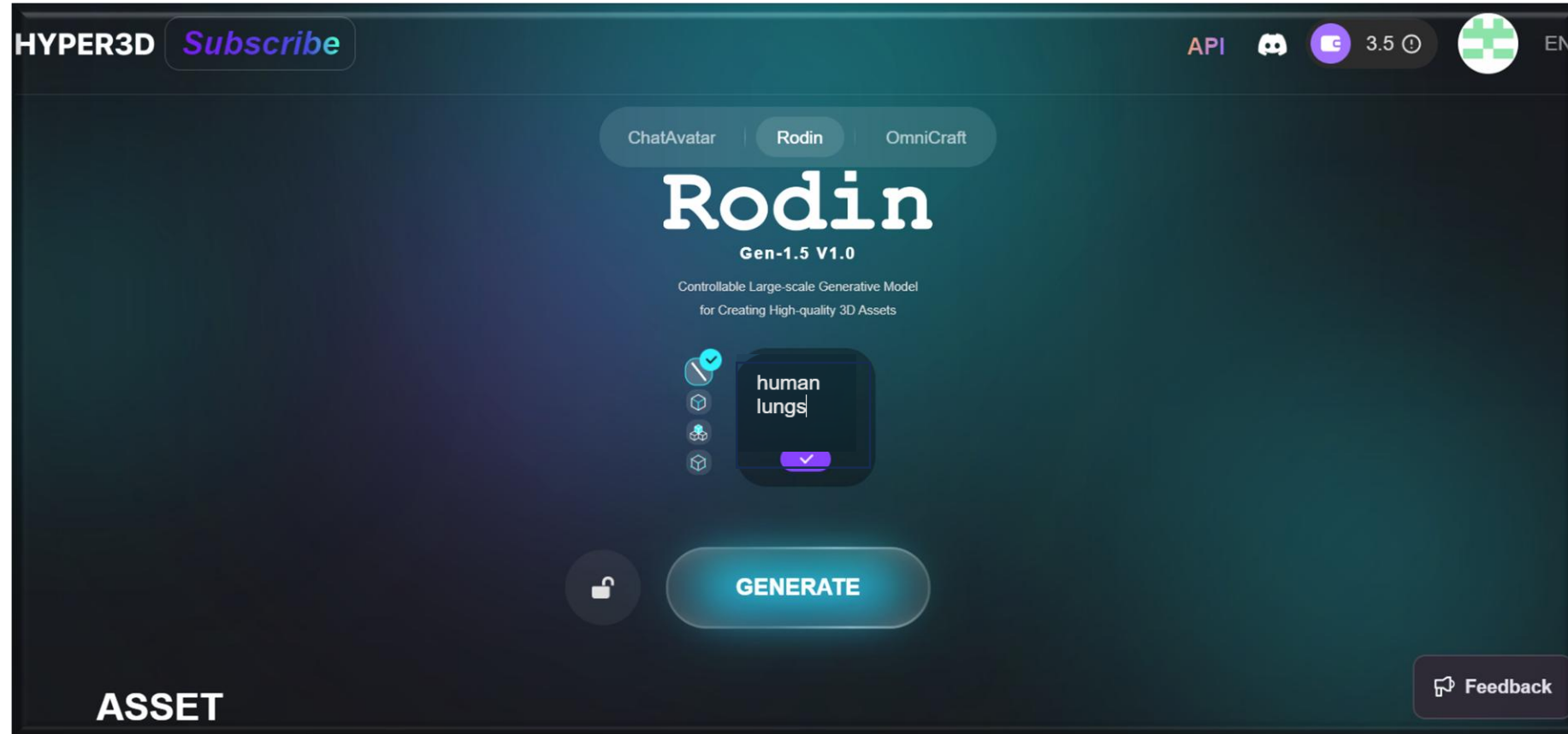


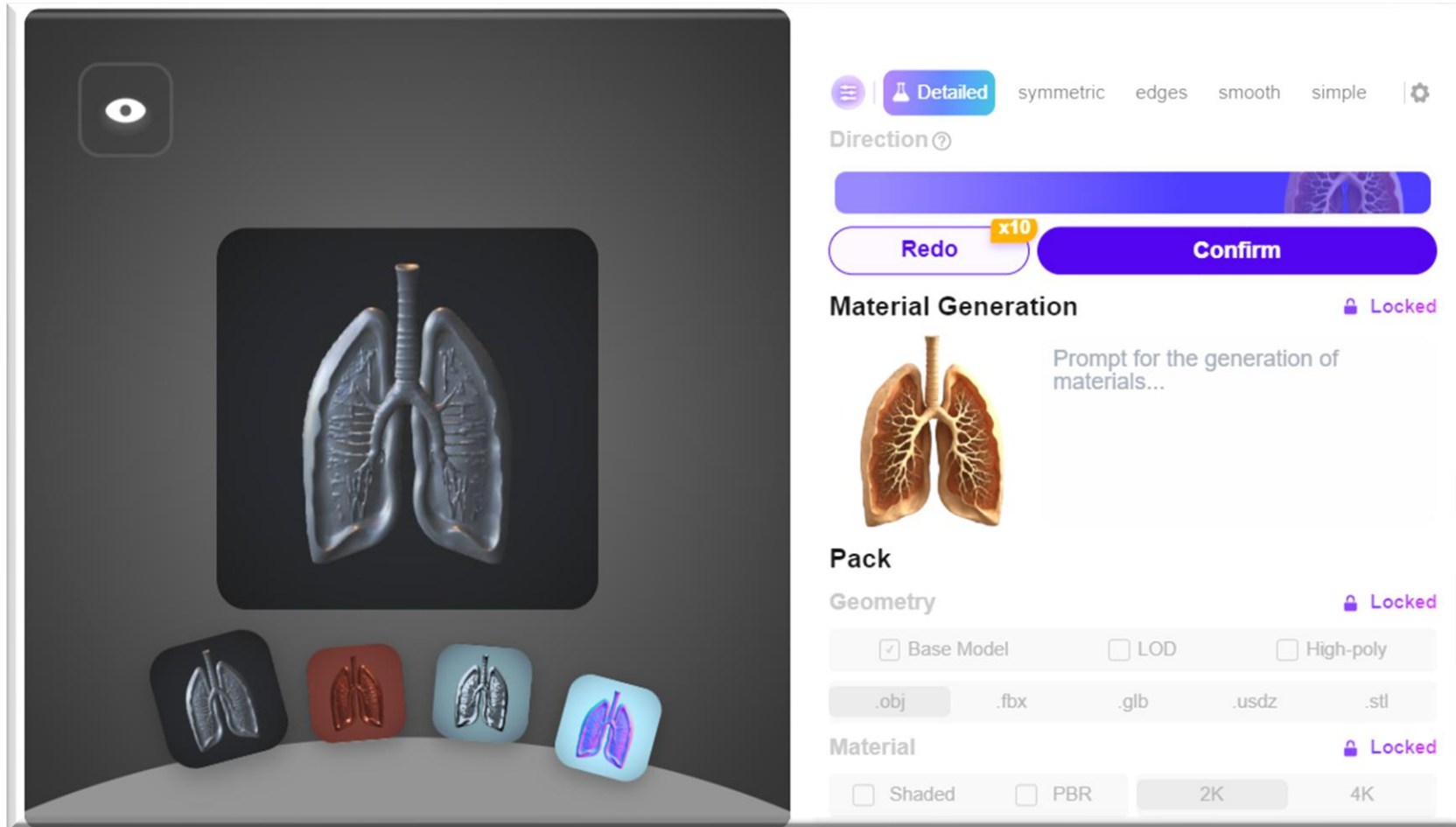
## Rodin AI

- Rodin AI is an advanced 3D asset generator. Rodin generates realistic 3D models.



# Input

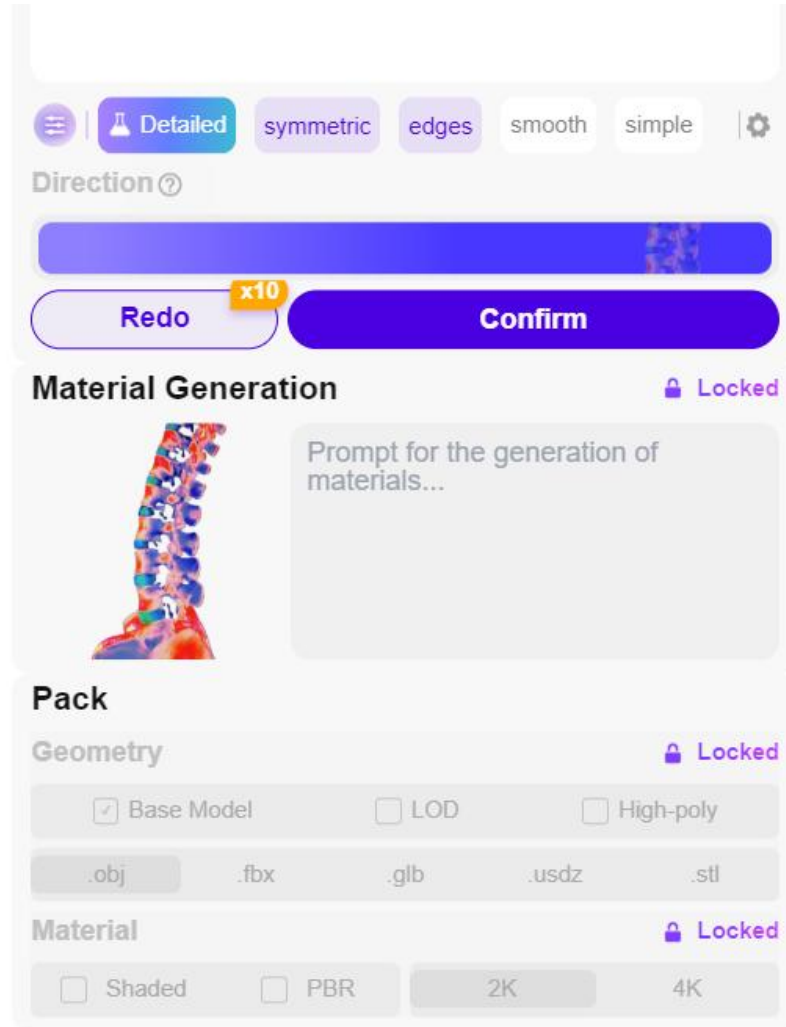
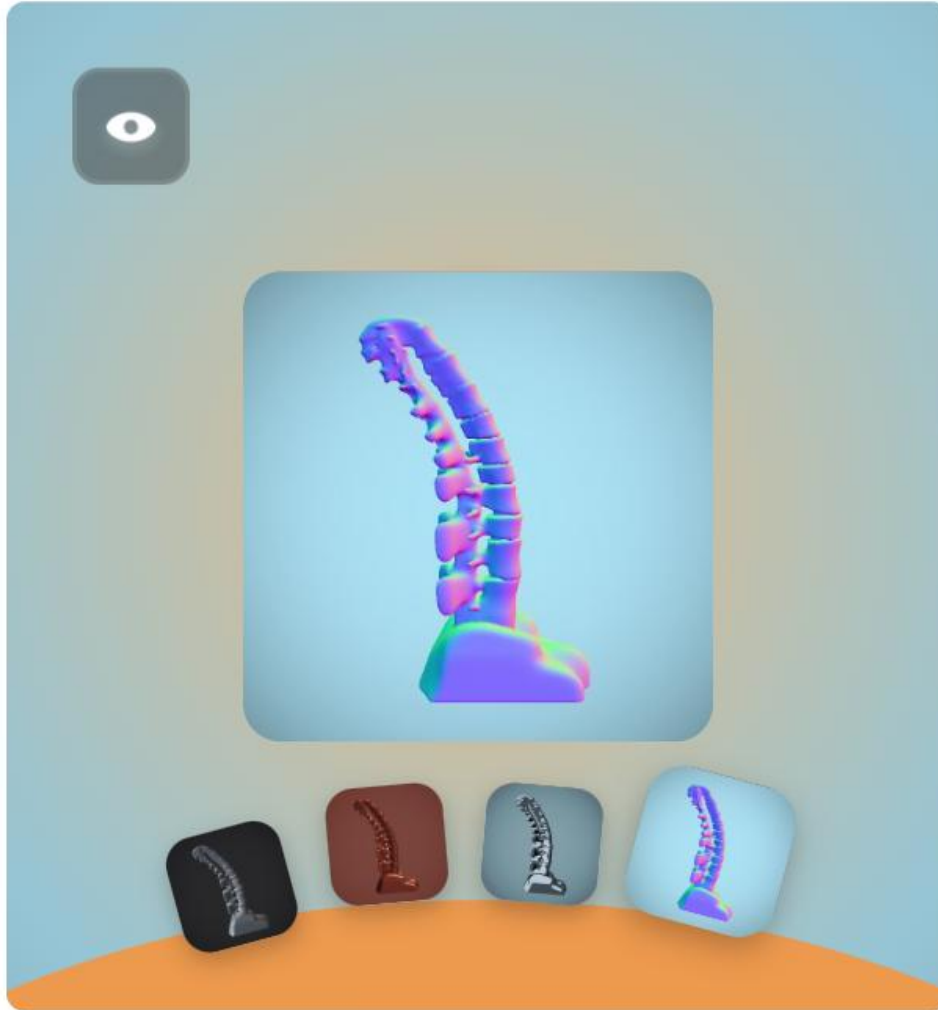






# Input







# SW Validation Execution

## Validate Input handling







## Validate Model Accuracy





## Validate Compatibility

- File Formats





# Cross Validation

## Testing







# Data Analysis





## Julius AI

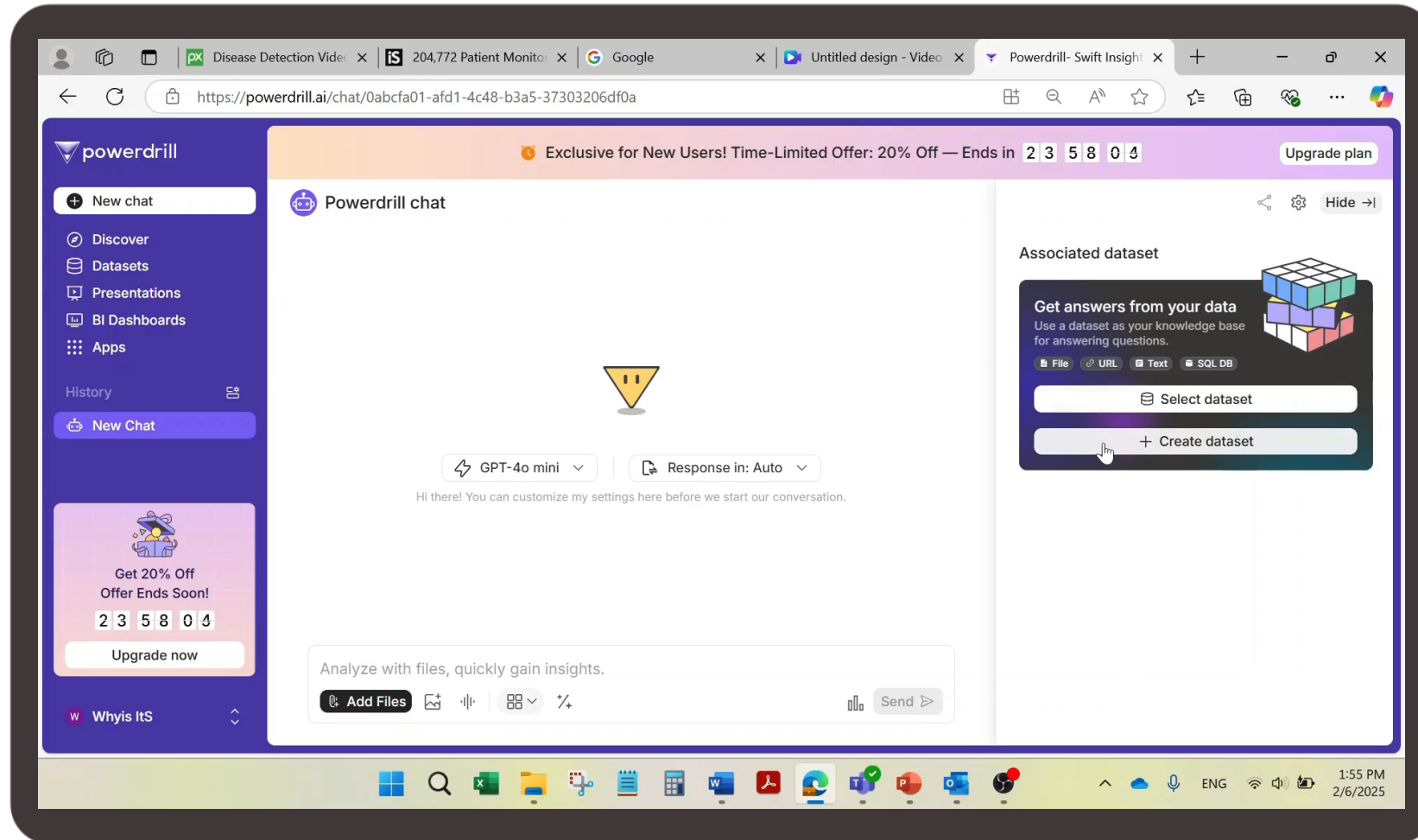
- An intelligent data analyst tool that interprets, analyzes, and visualizes complex data in an intuitive, user-friendly manner.



## **Powerdrill AI**

- AI service centered around personal and enterprise datasets, designed to unlock the full potential of your data.







# SW Validation Execution

## Ground Truth Testing



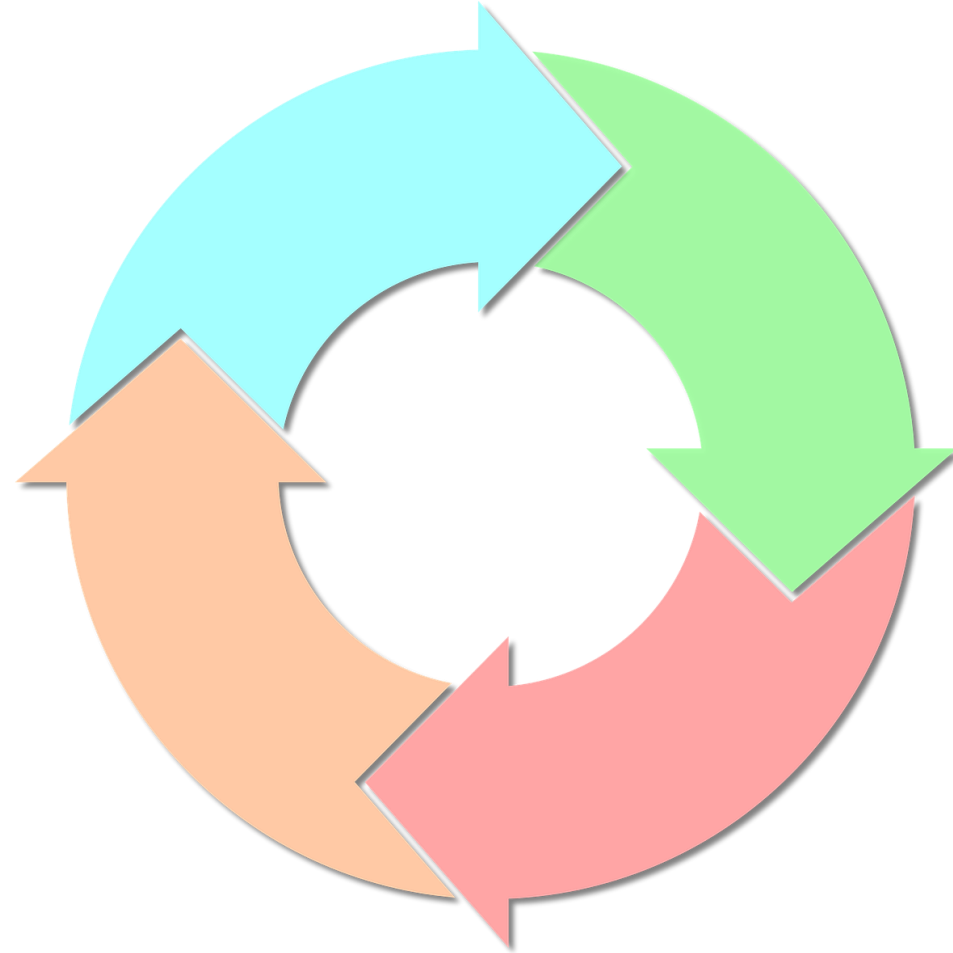


## Verify Data Inputs





## Verify Process Validation



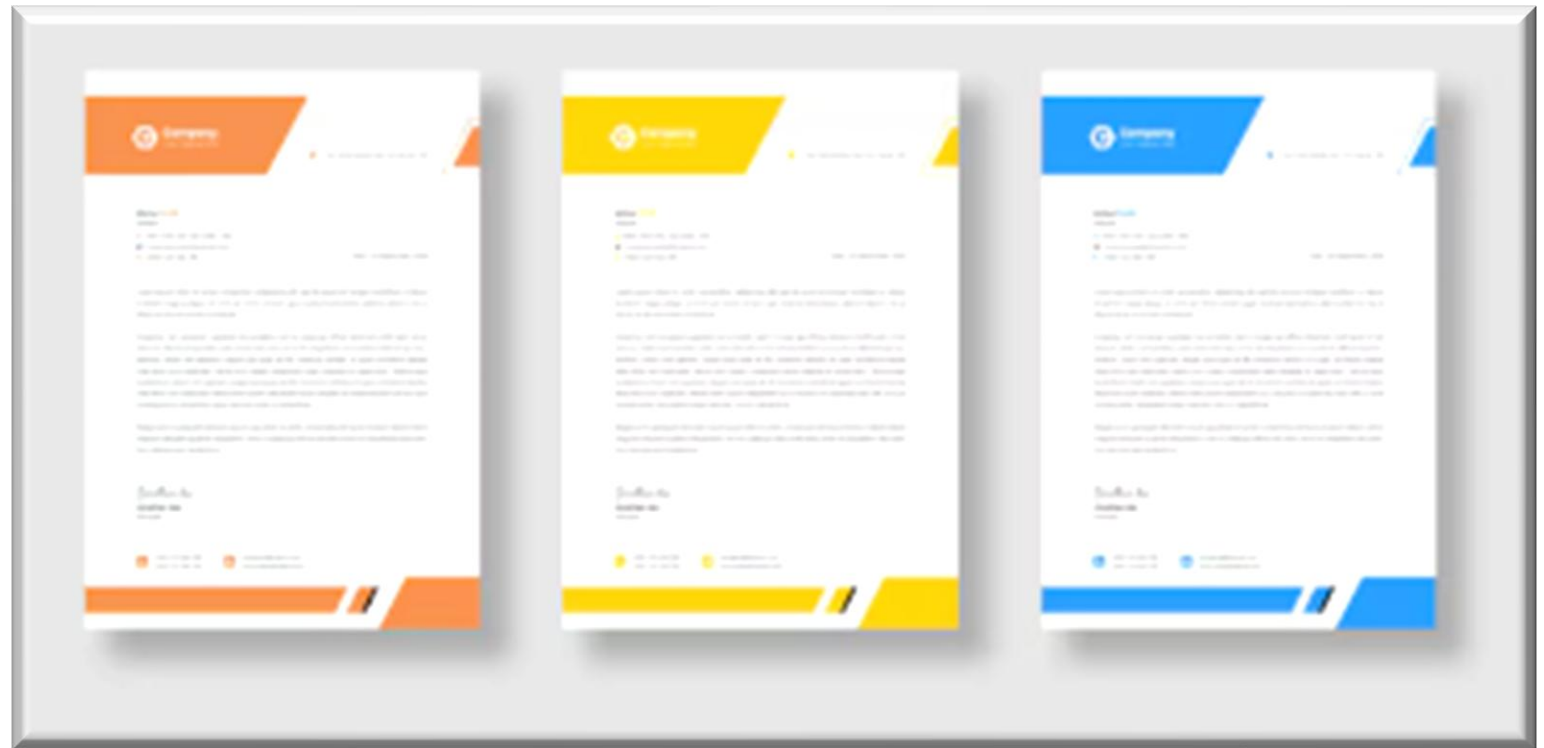


## Data Integrity Checks





## Data Formatting Checks











# Challenges



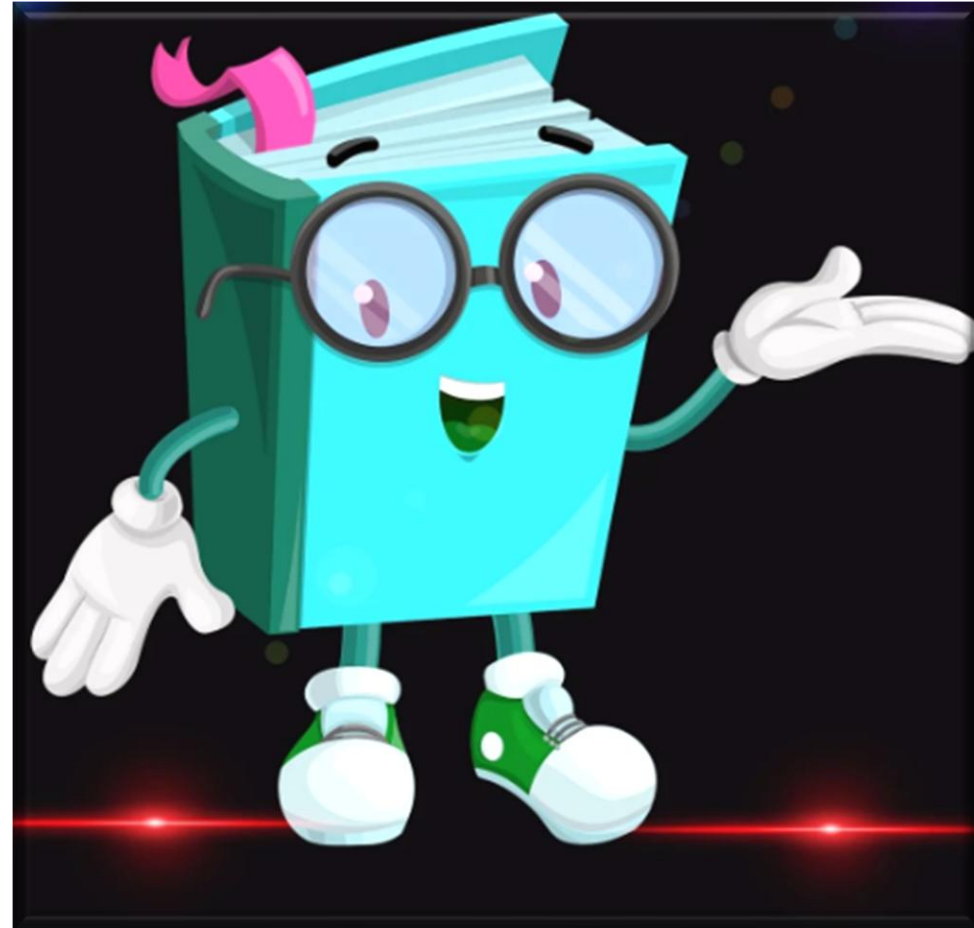


## Data-Related Challenges





## Lack of Explainability





# Dynamic Behavior





## Integration with Legacy Systems





## Real-World Testing Limitations







# Summary







# Summary – Regulatory Framework

## AI

- ISO/IEC 22989
- ISO/IEC 42001:2023
- ISO/IEC 23894:2023
- ISO/IEC 23053:2022
- ISO/IEC 25059:2023
- FDA - Artificial Intelligence and Machine Learning in Software as Medical Device



## Software Validation

- ISO/IEC 62304:2016
- ISO/IEC 90003:2004
- FDA's Premarket Submissions for Device Software Functions

## Cyber Security

- ISO/IEC 27001: 2022
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions



## SaMD

- FDA guidance on AI/ML in Software as a Medical Device (SaMD)
- IEC 82304-1: 2016
- ISO 14971: 2019
- ISO 27799: 2016



## Summary - Tools

### Cyber security

- Darktrace
- Cylance

### 3D Model

- Rodin AI

### Data Analysis

- Julius AI
- Powerdrill AI



# AI in Digital Health





# Q & A



# Yael Nuss



**Yael Nuss**



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*Thank  
you!*