DISSERTATION

At

CARPL.AI, New Delhi

Report on

How to Conduct a Clinical Trial of an Artificial Intelligence Model in Medical Imaging

By

Dr. Khushboo Arora

PG/20/023

Health IT management

Under the guidance of: Dr. Vinay Tripathi

POST GRADUATE DIPLOMA IN HOSPITAL AND HEALTH MANAGEMENT
2020-2022

International Institute of Health Management Research
New Delhi

Completion of Dissertation from CARPL.AI

The certificate is awarded to

Dr. Khushboo Arora

has successfully completed her Project on

How to Conduct a Clinical Trial of an Artificial Intelligence Model in Medical Imaging

on

15-JUN-2022

from

CARPL.AI

She comes across as a committed, sincere & diligent person who hasa strong drive & zeal for learning.

We wish her all the best for future endeavors.

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Title of the Dissertation/~~Summer Assignment~~	HOW TO CONDUCT A CLINICAL TRIAL OF AN ARTIFICIAL INTELLIGENCE MODEL IN MEDICAL IMAGING		
Plagiarism detect software used	"TURNITIN"		
Similar contents acceptable (%)	Up to 15 Percent as per policy		
Total words and % of similar contents Identified	12%		
Date of validation (DD/MM/YYYY)	30/06/2022		

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The Candidate has successfully carried out the study designated to her during internship training and her approach to the study has been sincere, scientific, and analytical.

The Internship is in fulfillment of the course requirements.

I wish her all success in all her future endeavors.

Dr Sumesh Kumar
Associate Dean, Academic and Student Affairs
IIHMR, New Delhi

Dr Vinay Tripathi
Mentor
IIHMR, New Delhi

Certificate of Approval

The following dissertation titled **"How to Conduct a Clinical Trial of an Artificial Intelligence Model in Medical Imaging"** at **"CARPL.AI Pvt. Ltd."** is hereby approved as a certified study in management carried out and presented in a manner satisfactorily to warrant its acceptance as a prerequisite for the award of **Post Graduate Diploma in Health and Hospital Management** for which it has been submitted. It is understood that by this approval the undersigned do not necessarily endorse or approve any statement made, opinion expressed or conclusion drawn therein but approve the dissertation only for the purpose it is submitted.

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Certificate from Dissertation Advisory Committee

This is to certify that **Dr. Khushboo Arora,** a graduate student of the **PGDM (Hospital & Health Management)** has worked under our guidance and supervision. He/ She is submitting this dissertation titled "HOW TO CONDUCT A CLINICAL TRIAL OF AN ARTIFICIAL INTELLIGENCE MODEL IN MEDICAL IMAGING" at "CARPL.AI Pvt. Ltd." in partial fulfillment of the requirements for the award of the **PGDM (Hospital & Health Management).**

This dissertation has the requisite standard and to the best of our knowledge no part of it has been reproduced from any other dissertation, monograph, report, or book.

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INTERNATIONAL INSTITUTE OF HEALTH MANAGEMENT RESEARCH, NEW DELHI

CERTIFICATE BY SCHOLAR

This is to certify that the dissertation titled " How to Conduct a Clinical Trial of an Artificial Intelligence Model in Medical Imaging" and submitted by Dr. Khushboo Arora Enrollment No. PG/20/023 under the supervision of Dr. Vinay Tripathi for award of PGDM (Hospital & Health Management) of the Institute carried out during the period from 7th March 2022 to 15th June 2022 embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other Institute or other similar institution of higher learning.

Signature

Annexure F

FEEDBACK FORM

Name of the Student: Khushboo Arora

Name of the Organization in Which Dissertation Has Been Completed:
CARPL.AI Pvt. Ltd.

Area of Dissertation: Pilot Clinical Trial for chest X-ray AI

Attendance: 100%

Objectives achieved: Data upload, CAD result upload, Reader's training
Reader co-ordination during a MRMC study.
Communication with stakeholders.

Deliverables: Timely co-ordinating a pelot study (MRMC, retrospective study and succesful completion of phase I and phase 2.

Strengths: ~~Goo~~ · Quick learner, Hard working and dedicated, Curious to learn new challanges.

Suggestions for Improvement: Excel skills

Suggestions for Institute (course curriculum, industry interaction, placement, alumni):
Should include more modules that are related to industry work i.e. Data Analytics and Excel.

Signature of the Officer-in-Charge/ Organization Mentor (Dissertation)

CARPL.AI PVT. LTD. New Delhi

Date: 29th June 2022
Place: Delhi

ACKNOWLEDGEMENTS

I would like to express my special thanks to **Dr. Anandhi Ramachandran (Associate Professor*)*** and IIHMR, Delhi for giving me the golden opportunity to pursue my dissertation at CARPL.AI, New Delhi.

I am using this opportunity to express my gratitude to everyone who supported me throughout the course of my dissertation at CARPL.AI, New Delhi.
I am highly thankful to **Dr. Vidur Mahajan (CEO),** CARPL.AI, for granting me the Opportunity for training and, for being helpful, supportive and receptive. His broad and profound knowledge, critical thinking has given me constant encouragement to achieve the task allotted and perform better.
.
Also, my successful completion of the tasks would not have been possible without the helping deeds from the entire department of CARPL.AI and especially **Dr. Vasantha Kumar Venugopal and Mrs. Kabita Dash** as they were always so cooperative and encouraging. Without their co-operation and warm attitude this project would not have been possible.

Special Regards to my mentor **Dr. Vinay Tripathi** (Professor, IIHMR Delhi) for his constant supervision and support in completing the projects.

Contents

Contents

ABBREVATIONS

AI	Artificial Intelligence
CARPL	CARING Analytics Platform
AUC	Area Under Curve
CXR	Chest X-Ray
CT	Computed Tomography
DICOM	Digital Imaging and Communications in Medicine
JSON	JavaScript Object Notation
MRMC	Multi-Reader Multi-Case
ROI	Region of Interest

ORGANIZATION PROFILE

About CARPL:

CARPL.ai is the world's first testing and deployment platform for medical imaging AI applications, which connects healthcare providers to third party AI applications, helping improve access, affordability, and quality of medical care.

It bridges the gap between healthcare providers and AI developers by serving as a gatekeeper that seamlessly connects both sides of the ecosystem. In essence, it is a single interface to access AI algorithms, validate and test them, and subsequently embed them into radiology workflows.

It is used by some of the world's leading healthcare providers, AI researchers, industry teams and startups. It is built with the single goal of making it easy for clinicians to get access to advanced analytics tools.

Vision

CARPL's vision is to be the back-end platform behind all medical imaging AI deployment globally by becoming the single interface for AI deployment at healthcare providers, and the go-to-market strategy of choice for AI developers.

Features

- CARPL's expansive feature-base ensures a multitude of use-cases across its users
- Imaging data management & search
- Data labelling, annotation and reading platform
- AI inferencing platform
- AI validation platform, including real-time validation
- AI deployment platform, including one-click RIS-PACS integration

Carpl.ai has two components attached to it that are useful in context of conducting a clinical trial:

1. **Service Component**: This includes Data Sources, Access to Experienced Radiologists and all the associated work related to coordination and administration to run clinical trial on AI algorithm effectively.

2. **Platform Component**:

Single Platform-Infinite Possibilities

The platform component of Carpl.ai has various aspects to it that help in successful completion of a clinical trial:

- Dataset management- The heart of CARPL – Store, search, curate data → A single platform for all your image and metadata management needs
- Algorithm: This contains list of all the algorithms under CARPL.

- Annotation: Built for radiologists by radiologists, CARPL offers the industry's fastest medical imaging annotation platform and integration with 3rd party tools such as ITK SNAP, 3D Slicer and Radiant DICOM

DISSERTATION REPORT

Problem Statement

AI has had a significant impact on a variety of tasks and businesses in recent years, and its acceptance appears to be increasing. By 2030, according to McKinsey, AI will result in a $13 trillion increase in GDP. Although AI usage is increasing, it should be underlined that it has not yet reached the traction it deserves. One of the causes is the time it takes for businesses and clients to assess the risks of implementing AI-related technology. Additionally, businesses must assess the risks of upgrading existing systems against the commercial benefit AI technologies provide.

An AI pilot project might be a useful beginning point for an AI journey because all firms are starting from scratch. It assists in swiftly validating use cases, assessing risks, and calculating ROI. The lack of clear commercial objectives and outcomes causes the majority of early AI efforts to fail. Stakeholders buy-in and support for the project is made easier by clearly outlining the desired outcome and identifying success criteria. Because this will be the company's first engagement using AI, the pilot project must be completed in a short period of time, ideally within 3-6 months. The main aim of a pilot project is to serve as a starting point for future implementations, rather than to solve any fundamental concerns.

During a pilot project, the stakes are usually high. Make sure the initial goals are reasonable, because if the first AI project fails, the organization's future AI endeavors may be put on hold indefinitely.

When beginning your pilot project adventure, it's best not to set your sights on hard results or immediate financial rewards. Instead of striving for anything enormous, start with a narrow scope and strive for soft goals like process improvements, improved customer happiness, or increased efficiency.AI pilot initiatives are likely to offer lessons that can be used to guide future or subsequent projects.

The number of resources required changes depending on the project requirements, as it does with all projects. If a company lacks an experienced AI team, it's best to collaborate with a skilled external partner to successfully complete the AI pilot project.

A capable leader is essential to effectively direct the team, who can liaise between AI and domain/industry specialists, which is where platform as a Service comes into play. It allows everyone to communicate more effectively and stay on the same page when it comes to the pilot project's goals and outcomes. A huge volume of high-quality, dependable data is required to successfully deploy an AI project. Data is the foundation of any AI project since the intelligent system 'learns' by analyzing large amounts of data over time. Furthermore, employing data that is more static and does not change frequently aids the algorithms in producing consistent findings. It's important to remember that AI can't tell the difference between good and bad data on its own. When given bad data, an AI system will produce inconsistent and frequently incorrect results. As a result, in order to be successful with the AI pilot project, it is critical to use a huge collection of accurate content.

Although AI pilot projects are intended to be basic and manageable, they nonetheless necessitate a significant amount of skill and the appropriate resources to be implemented successfully.

Selecting and launching an AI pilot project can be frightening, but if you wait too long, you risk

falling behind your speedier competition.

Thus, **the purpose of this study is to tell how to conduct a pilot study/clinical trial of an Artificial Intelligence model in Medical Imaging.**

Scope of Project

Milestones

Milestone	Description
M1	Data (provided by client) successfully loaded in reading tool and functionality of the tool (as defined in "Requirements for Reading Tool") provided by CARPL and tested by client
M2	Reader Training Completed
M3	First Reading Session Completed
M4	Second Reading Session Completed

Purpose and Summary

Key question for the pilot	**What AUC Effect Size can we achieve with optimal study design and execution?** ● Improved reader training to promote trust in AI results and acceptance of true positive AI marks ● Latest algorithm version (V9) and optimal operating point ● Simultaneous evaluation of 2nd reader workflow and concurrent reader ● Robust ground truth (lateral CXR and paired CT as reference) ● Focus on pulmonary lesions as target finding ● Reading and truthing tool modifications
Reasons for pilot	Generate data to determine sample size parameters for pivotal MRMC study ● Avoid Effect Size over-estimation (risk of study failure) ● Avoid Effect Size under-estimation (study costs too high) ● Validate if acceptance of reader marks improves in 2nd vs. concurrent reading ● Provide reliable parameters for estimation of sample size
Target finding	**Pulmonary lesions** (pulmonary nodules < 3cm and masses >= 3cm)
Image input data	DICOM CXR in Posterior Anterior projection (upright films) Multi-vendor data including Siemens, GE, Philips etc.
AI input data	AI boxes can be read from JSON format. The JSON will include information about box location (width, height, center) and AI confidence (integer between 6 and 10)
Readers	**7 US board certified radiologists with a diverse range of experience (including experienced and novice radiologist)**
Reading sessions	**2 reading sessions** separated by at least 4 weeks washout. Reading sessions are "unaided/2nd read" and "concurrent read" See Figure 1.

Reading tool	CARPL
Special needs for training session(s)	Dedicated training session based on presentation and exploratory usage of the reading tool with example cases. This may cover CXR and CT. CT is 2D slice viewing only (MPR if possible), no measurements or quantifications. Remark: CT viewing is optional, if it involves additional efforts it is not required
Statistical analyses	● Concurrent *vs* second reader ● Superiority claims for detection of Pulmonary Lesions in AI-assisted reading ● Primary Endpoint Is Case level superiority in detection accuracy for nodules and masses. ● Additional analyses will be on instance level detection accuracy See Table 2 with key data to be collected in the study and Table 4 with potential sources of error impacting data quality.
Results	Sample size parameters for pivotal MRMC study
Timeline	Start: immediately Finish: Target before March 31st 2022.

Requirements for Reading Tool

This section gives requirements on the reading tool provided by CARPL. First the necessary data inputs that need to be collected from each reader are detailed in Table 2. These inputs need to be collected in the

- unaided reading mode
- aided-second reader reading mode
- aided-concurrent reading mode.

Then the workflow requirements of the tool are provided in Table 3. Potential sources of error are detailed in Table 4, which require mitigation, e.g., by respective pop-ups or by prohibition by the software.

Table 2. Key data to be collected in the pilot study (unaided, 2nd read, aided)

Level	Name	Description
Instance Level (per lesion)	Findings_box	Box location for each instance representing a nodule or mass (with center, width, height of box)
	Instance_level_confidence_score	Instance-level confidence score of each box from 1-100 with "100" meaning the reader is 100% certain that a nodule or mass is present and "50" meaning the reader is 50% confident that a nodule or mass is present. Increments can we in steps of 1 or steps of 10. Implementation could be a dropdown menu or a popup whenever a new box is drawn.

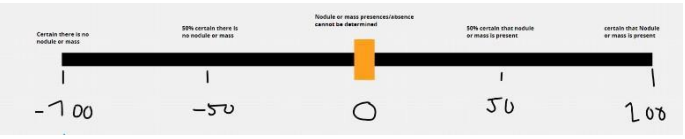
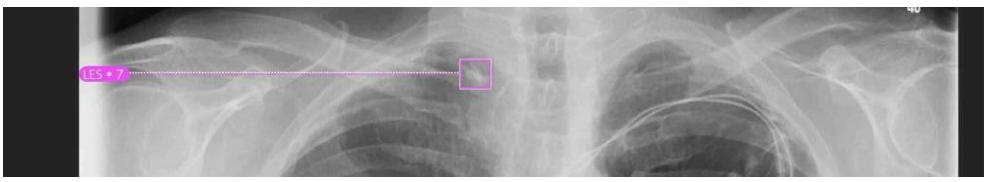
Case Level (per image)	Case_level_confidence_score	Case-level confidence score regarding the presence of a nodule or mass with a range from –100 to 100 using 1 point increments. For each case, the starting point is "0". Scale: ● 100 means: 100% certain that nodule or mass is present ● 50 means: 50% certain that nodule or mass is present
		● 0 means nodule or mass presences/absence cannot be determined ● -50 means 50% certain there is no nodule or mass present ● -100 means 100% certain there is no nodule or mass 

Table 3. Workflow requirements

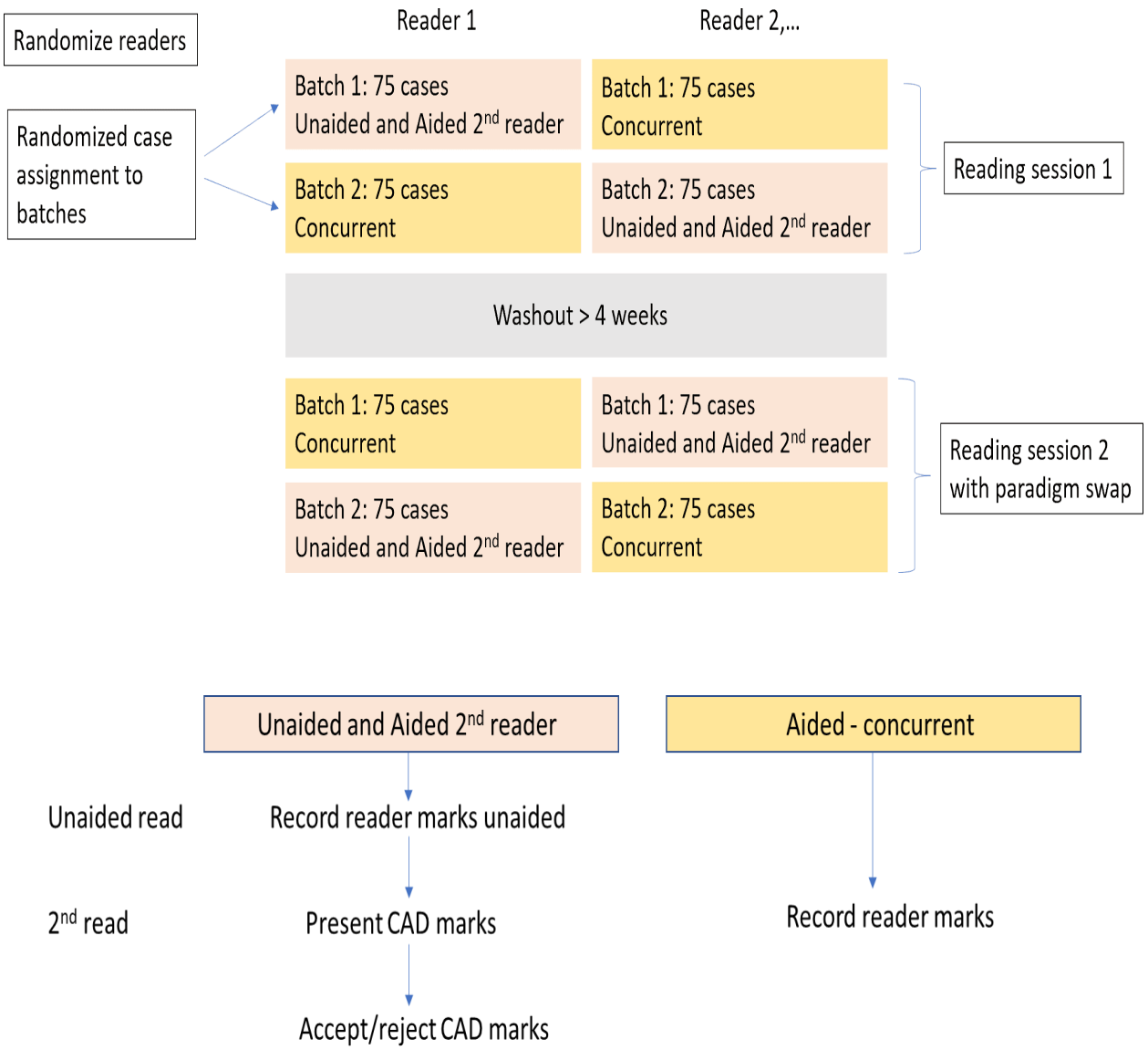
Name	Description
Unaided Reading Mode	The tool must support the unaided reading mode, where the user assessment of the case (as defined in table 2) is collected without help of AI
Aided Second Reader Mode	The tool must support the aided second reader mode. In this mode, the AI results are displayed directly after the unaided reading mode was finished. The changes in reader assessment after the AI results are displayed, need to be collected (as defined in table 2)
Aided Concurrent Reader Mode	The tool must support the aided concurrent reader mode. In this mode, the AI result is displayed once the case is loaded. The reader's assessment needs to be collected (as defined in table 2)
Display of AI results to the user	Overlay on top of the original CXR image (AI boxes and AI confidence score). Different format for AI marks vs user marks, e.g., different color and line style for the box. AI boxes of the product are attached below 
Display of Confidence score	The confidence score of the AI algorithm (integer number between 6 and 10) should be displayed for each box.
Interaction with AI results	Users should be able to accept/reject AI results. If rejected, the box will be deleted. If accepted, the AI mark turns into a user mark and user should be able to change the size of the box and assign an instance-level confidence score.
Reader-Assist Tools	Do we have the option of including basic imaging tools that radiologists routinely used during reading, i.e., windowing, brightness/contrast adjustment, measurement tool? Is this a possibility?

Toggle of all Reader Marks	Overlay should have a toggle functionality to turn the overlay on and off for all marks (user marks and AI marks).
Monitor Setup	The reading must be performed on a medical graded high-resolution monitor

Table 4. Potential sources of error impacting data quality

Reader assigns a positive Case_level_confidence_score, however, no Findings_box is box drawn	High impact if happens
Findings_box indicating the presence of a nodule is drawn, and user wants to give negative Case_level_confidence_core	Medium impact
Case_level_confidence_score is negative, and reader wants to draw a box	Medium impact
Case_level_confidence_score is positive and user deletes all Findings_box(es)	Medium impact
User not reviewing each AI mark	
User having access to AI results during the unaided read	Incorrect results for unaided read
Not recording data from the unaided read before showing AI marks in the 2nd reader workflow.	Impact: data from the unaided read incorrect
User misses to turn AI marks on for the 2nd read	Incorrect data for 2nd reader workflow

Figure 1: Visualization of reading workflow



Review of Literature

MarkIt: A Collaborative Artificial Intelligence Annotation Platform Leveraging Blockchain for Medical Imaging Research

The quantity and quality of input data are critical in today's medical image processing studies. Well-annotated datasets are required for supervised machine learning algorithms in particular. The lack of annotation tools makes it difficult to set up systems with scaled processing and a suitable incentive mechanism. This tool is a web-based platform was created for group annotation of images from medicine, using artificial intelligence and blockchain technology. With the aid of this program, users can easily annotate images for object recognition and classification on both DICOM and non-DICOM images. It can help speed up the annotation process and keep tabs on user conduct so you can compute the right reward. In a proof-of-concept research, three fellowship-trained radiologists did annotations for multi-label categorization and 1,000 chest X-rays were taken. After evaluating the trans agreement and determining the worth of the dataset, the compensation for annotators is dispersed using a cryptocurrency. The application facilitates the lengthy process of annotation and may one day be used as a foundation for identifying the worth of data and leveraging the outcomes of annotation in a more scalable way.

ePAD: An Image Annotation and Analysis Platform for Quantitative Imaging

Medical imaging is crucial for determining how patients respond to new cancer treatments. It takes time to examine quantitative lesions on pictures, and it's difficult to incorporate new potential quantitative imaging biomarkers of response in clinical trials. Imaging professionals can compare and review a myriad of quantified imaging biomarkers computed by ePAD to spot possible candidates for clinical trial surrogate endpoints. Through reports summarising variations in tumour burden based on various imaging variables for clinicians, ePAD offers clinical decision - making tools for tracking cancer response. As a process management and research supervision tool, it enables clinical trial project managers to establish worklists for users and monitor the status of annotations provided by research groups. To enable interoperability, ePAD stores all image annotations and quantitative imaging findings of the study in conventional file formats and supports the transfer of markings from different application formats. ePAD features a plugin architecture that supports MATLAB server-side modules in addition to client-side plugins, allowing the community to enhance the ePAD platform in a number of ways for new cancer application cases.

LesionTracker: Extensible Open-Source Zero-Footprint Web Viewer for Cancer Imaging Research and Clinical Trials

For evaluating participant inclusion and response to therapy in oncology clinical trials, image-based alternative objectives have expanded in importance. As therapeutics have progressed and multiplied, the malignancy metrics variables used to evaluate treatment response have grown in diversity and precision. The demands for timely and efficient results reporting and also the increasing complexity of image-based response evaluation make it challenging for site radiologists to adequately meet local and multicenter imaging demands. These constraints accentuate the necessity for fully advanced cancer imaging informatics tools that can help enable procedure picture evaluation while also enhancing reviewer performance. This tool is an open source, zero-footprint image processing viewer with both the potential to be incorporated into third-party systems for sophisticated imaging tools and clinical trial informatics platforms. It was created specifically for oncology clinical trial procedures.

RIL-Contour: a Medical Imaging Dataset Annotation Tool for and with Deep Learning

Deep-learning algorithms are supervised artificial intelligence algorithms that "learn" from labelled data. For optimal model convergence, deep-learning models require vast, diverse training datasets. The time and effort required to curate large datasets is commonly considered a roadblock to the development of deep-learning algorithms. RIL-Contour was created to speed up medical picture annotation for and with deep learning. One of the main goals of the software's creation was to build an environment that allows clinically focused users to employ deep-learning models to quickly annotate medical images. To annotate medical imaging with voxel and/or text annotations, RIL-Contour provides completely automated deep-learning approaches, semi-automated methods, and human methods. RIL-Contour encourages picture annotation standardization across a dataset to reduce annotation error.

DeepLNAnno: a Web-Based Lung Nodules Annotating System for CT Images

Lung cancer is one of the most frequent and deadly cancers, and lung nodule identification is critical for early detection and diagnosis. While requiring a large amount of labelled data, a supervised learning model which has been adequately educated can assist healthcare providers in detecting nodules on CT scans. However, existing annotation methods are insufficient for identifying pulmonary nodules in CT scans. DeepLNAnno is a web-based lung nodules annotation system that offers a three-tier working procedure and a slew of capabilities, including semi-automatic annotation, that not only make it easier for doctors to annotate than previous systems, but also improve the labelling accuracy. The trials showed that a suitable nodule-detection system was constructed, a good benchmark scores on evaluation data were attained.

Background of Project Implementation

Medical ML and AI researchers seek to enhance their models by incorporating more data rather than simply changing the algorithm architecture as the discipline of supervised machine learning (ML) and artificial intelligence (AI) expands. Because imaging can be non-diagnostic and intra- and inter-observer variability is considerable in medicine, it's vital to have high-quality annotations. Approximately 25% of radiologists disagree with other radiologists' diagnoses, and 30% disagree with their own former assessments. Learning models rely on labelled "soft" ground truth because ultimate ground truth, like patient records, is not always available. Preconceptions from inadequately annotated datasets may well have huge implications for machine learning approaches in therapeutic applications. For decades, researchers have looked into crowdsourcing annotations, particularly how to deal with noisy labels. However, there have been few collaborative annotation platforms for AI/ML systems that can handle medical imaging datasets accessible to far.
Improving the database's quality necessitates the involvement of well-trained specialists and a robust curation procedure based on voluntary commitment. It's vital to remember that crowdsourcing data gathering methods might be readily tainted by people who aren't properly trained. Consider how quickly the value of the data or the correctness of the annotation may be calculated. In this scenario, researchers and vendors can exchange or trade datasets to create a top-notch dataset with an acceptable mix of positive attributes for AI training. Furthermore, this transaction can be objectively assessed and tracked in a secure manner. CARPL.AI, is the subject of this research project.
The platform will be used to make early annotations of datasets for classification tasks utilizing both aided and unaided datasets in the experiment.

Overview

S.No	Item	Description
1	Reading Services	Professional fee of readers
		Lead Reader honorarium
		Reader Training charges
		Reading coordination and support
2	CARPL Annotation Platform	Base platform fee for readers (7 readers, 150scans per reader, 2 reading sessions
		Platform customization
		Cloud Hosting & Infrastructure Cost
		AI Output Integration
3	Others	Administrative fee, maintenance, and support

Timeline

CARPL will endeavor to complete the study within 90 working days of payment of 1st Milestone subject to timely availability of data and protocols from client.

Milestone	Description	Milestone details	Owner	Timeline
M1	Data (provided by Sponsors) successfully loaded in reading tool and functionality of the tool (as defined in "Requirements for Reading Tool") provided by CARPL and tested by Sponsors	Update CARPL with all technical input	CARPL	10 days
		Sample data shared	CARPL	3 days
		Functionality tested by Sponsor	SH	3 days
		Load data on CARPL	CARPL	5 days
M2	Reader Training Completed	Train readers with sample data	CARPL	7 days
M3	First Reading Session Completed			21 days
M4	Second Reading Session Completed			21 days

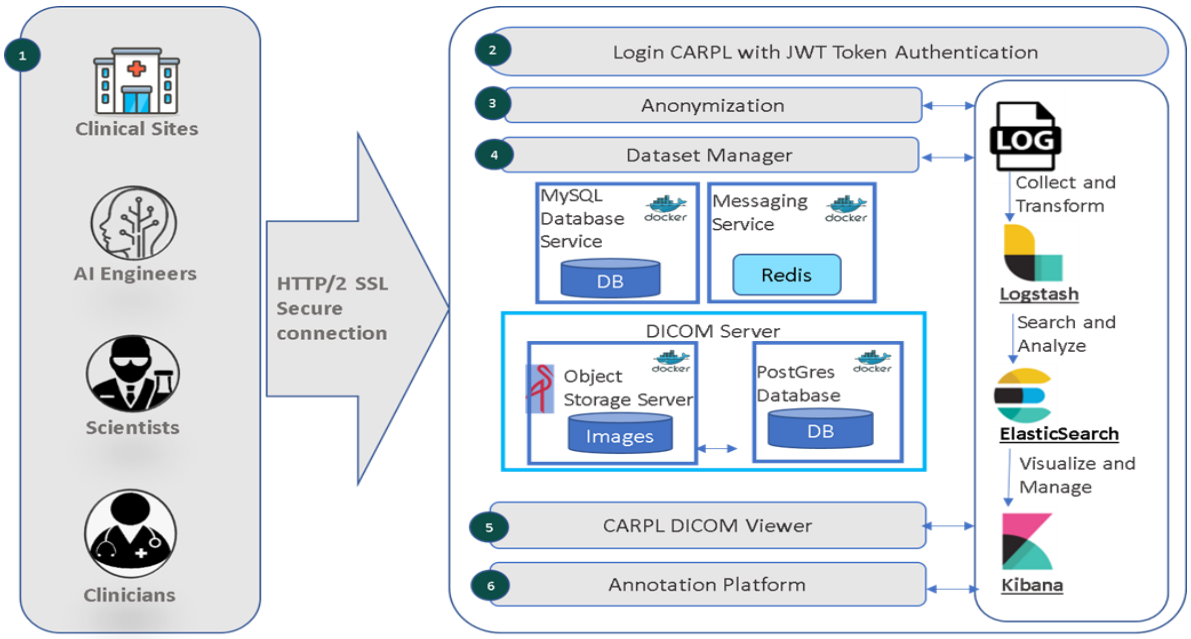
Wash out period of 4 weeks to be accounted between M3 and M4

Scope of work

- Recruit seven readers for the Study - 7 US board certified radiologists, 4 readers with less than 4 years of experience, 3 readers with more than 4 years of experience reading Chest X-rays. Two reads per reader as per supplied protocol.
- End-to-end coordination of the study between Sponsor and readers
- Provide a technological platform (Reading & Truthing tool) for running the study as per study protocol.
- Data ingestion, including DICOM images and corresponding AI outputs (supplied by Sponsor) along with orchestration of study viewing as per the protocol.
- Study output data would be provided to Sponsors in a mutually agreed format.

Methods

Using a modern web browser, the platform is now available online, without the need to download or install any additional software. Users must have a valid internet connection and create an account in order to access the site. The platform has been built, as shown in Fig. below, with numerous modularized features.



CARPL comes in-built with a fully-functional DICOM Viewer with an annotation platform that allows radiologists who are either reviewing the findings of an AI algorithm, or independently testing an AI algorithm, to document their findings in a simple yet comprehensive way. The radiologist can easily edit, add or delete the pixel level annotations within the CARPL viewer and save changes CARPL also gives AI developers and radiologists the ability to define input text fields for radiologists to fill as they go about the validation process. This is extremely critical for enhancing communication between the radiology and data science teams since often there are comments that the radiologists might want to share with the data science team.
The annotations performed by radiologists can be downloaded as JSON files by the AI developers and incorporated into their development pipelines.

I was actively involved in training the radiologists to utilize the features of the platform efficiently.

- **Demo sessions**
- **Data curation and cleaning**
- **Uploading the data on to the platform**
- **Gathering requirements for customization of platform as per clients' needs**
- **Creation of annotation templates and projects**
- **Tracking the annotation status**
- **Providing support 24*7**

How the platform was utilized by me to conduct the clinical trial is explained below in further details:

Following the basic steps, one can create an annotation template that can be later linked to annotation project.

 Click on "**Annotation - Annotation Template**" from the left panel
 Select "**Create Template**" from the top right corner
 Provide "**Template Name, Template Description, and ROI Labels** "
 ROI Labels can be selected from the dropdown menu or can be created.
 Drag elements from "**Form elements**" boxes and drop it in the form builder box
 Users can create a copy of a form element and edit according to the requirement.
 Edit the "**Form elements**" if required.
 User can select "**Required**" to mark mandatory.
 "**Preview**" to review the template before saving the template
 "Save Template" to save the annotation template

CARPL offers three different methods for importing imaging data. However, users can select the import method depending on the type of data, the size of the dataset, and the available resources. All of these options get data into CARPL.

This will give an overview of each option for importing data and steps for determining which method is best for the appropriate type of data.

1. **DICOM Push**: Connects CARPL with PACS to upload data directly. Configure DICOM Nodes on PACS to send data.

- Click on “Dataset Manager - My datasets” in the left panel to get a snapshot view of all datasets created by the user.
- Select “CREATE DATASET” from the right top corner of the “Dataset Manager - My datasets” page
- Provide Dataset Name, Dataset Description, modality to create a dataset.
- Leave the “modality” blank to accept multiple modality cases
- Click on the “CREATE DATASET” button to create a blank dataset and redirect to the Dataset detail page
- Enable “DICOM Receive”. The system will provide "AE Title" and "Port" information. This will create a channel/connection to send data to CARPL.

2. **CARPL Console**: The CARPL Console is a web application where you can upload and view your data. Use this option for a quick way to upload smaller datasets (about 200 MB per upload). There are a couple of ways to upload data in the CARPL console:

   The DICOM uploader allows raw, uncompressed DICOM data to be added to a dataset.

- Click on “Dataset Manager - My datasets” in the left panel to get a snapshot view of all datasets created by the user.
- Select “CREATE DATASET” from the right top corner of the “Dataset Manager - My datasets” page
- Provide Dataset Name, Dataset Description, modality to create a dataset.

- Click on the “CREATE DATASET” button to create a blank dataset and redirect to the Dataset detail page
- Click on the “Upload DICOM files / Upload DICOM folders."
- After selecting the images, select “START UPLOAD” to initiate the upload process
- DICOM / JPEG / PNG/ RVG files are allowed for X-ray modality, and only DICOM files are permitted for all other modalities.
- Users can upload folders containing DICOM as well.
- Only selected modality images are allowed if selected during “CREATE DATASET.”
- In-browser anonymization to de-identify studies at your end. Only DICOM file names are preserved for backtracking
- System will provide a mapping csv file with actual studyID/patientID and anonymized studyID/patientID for reference
- After upload, the user can visualize the status of the upload i.e., success, Failure, Duplicate, and Invalid DICOM

3. **CARPL API:** Imports studies through the CARPL upload studies API available under dataset section https://documenter.getpostman.com/view/12410320/T1LV8iyD?version=latest#03db1c69-0cdd-4272-80b7-c9f80cfea0e3

User can share the complete dataset and individual study as well by using the share options.
User can choose how many panes/view with study images he/she wants to preview. User can choose from one to nine panes for different images. For example: if a user wants to see four images he/she can select 2x2 screen layout.

Upon clicking download icon user can see all download options like download all logs, annotations, Annotation ROI as JSON and CSV file and user can also deselect options as per the requirement. Clicking on “**Download**” button will provide a zip file with three csv files and one JSON file.
CARPL is developed to optimize annotation workflow, especially in large-scale datasets with multiple collaborators and stakeholders, and their roles were taken into account when designing the platform.

Assign Reviewer

- Select studies and then click "**Assign reviewer** ", to assign reviewer(s). Write email ids of the reviewer(s) click "**assign**".
- The reviewers will be notified via email.

Assign to myself

- Click on “Assign to myself” to assign studies to the logged-in user for annotation
- The annotators will be notified via email.

Remove Reviewer

- To remove a reviewer from all the studies, select email id from the dropdown box against “**Remove**” icon. This will show all the studies for the selected reviewer. Then select the study / studies and click on “**Remove**” icon.
- Select the ‘X’ against the reviewers name to remove annotator from the study.

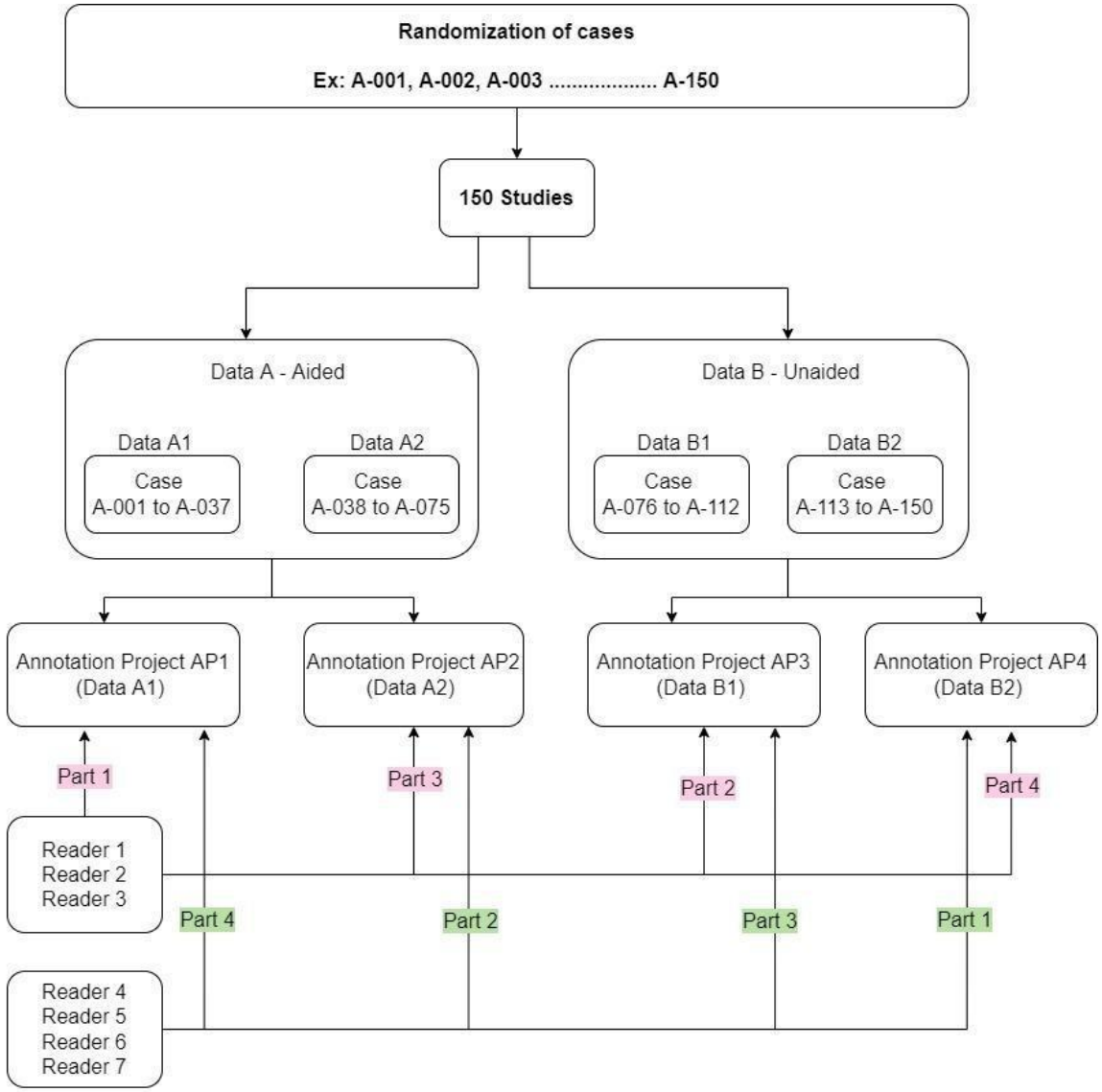
We can also use this mode for training or education. It features a combination function that avoids unnecessary mistakes and pre-training sessions using the review mode before implementing the main project. In pre-training sessions, users can use CARPL's review mode to swiftly examine and remedy their discordance problem.

Finally, the presented platform includes a function of tracking annotations that can help adhere to stringent project timelines.

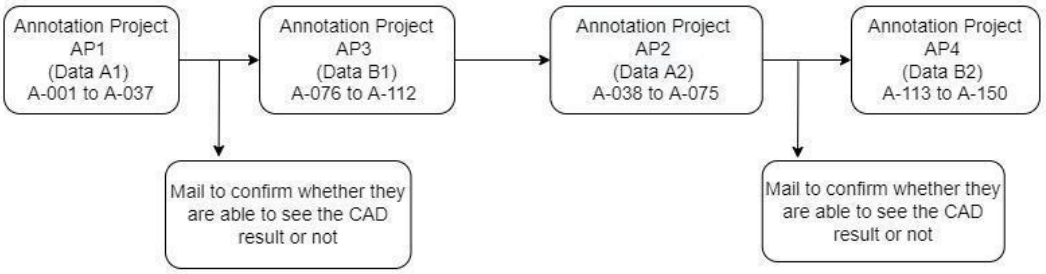
Screenshots and Flow Diagrams

The study was conducted through CARPL platform and below are the screenshots and flow diagram that provide an overview how platform features were used to conduct the clinical trial.

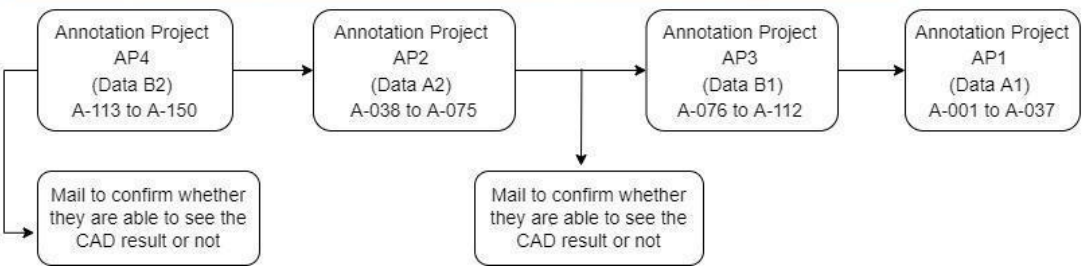
This workflow was created to aid in conducting a clinical trial and follow a standard protocol throughout the process.

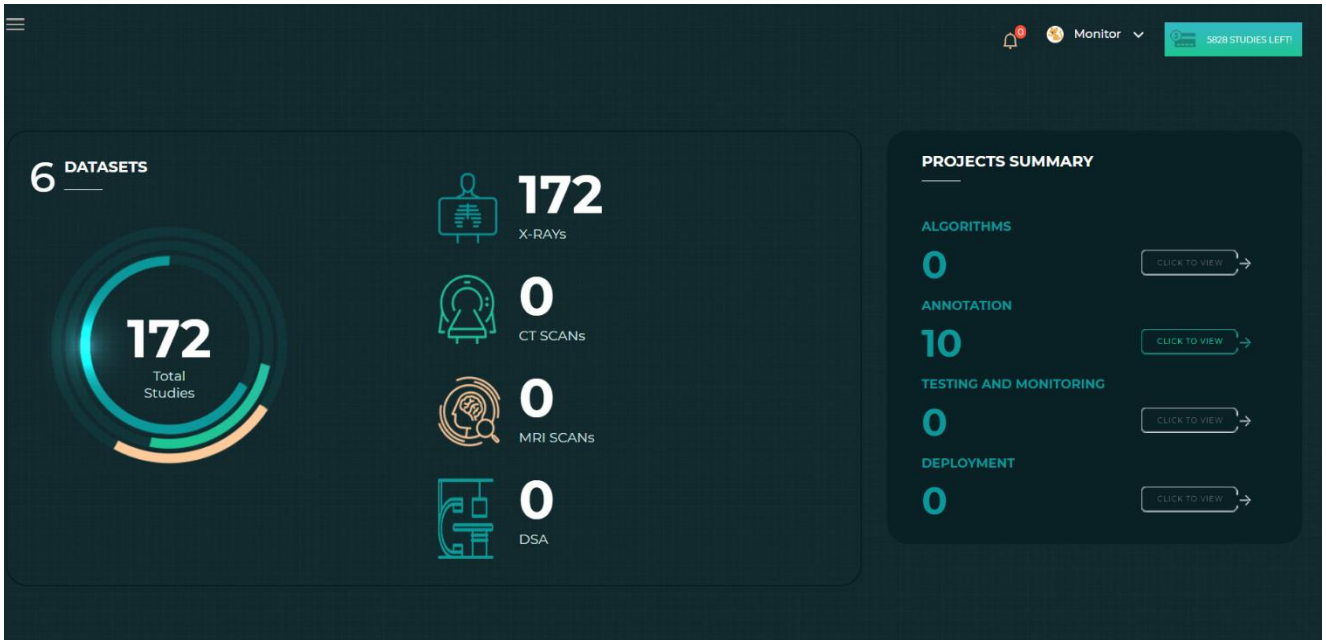


Reader Group 1 (Reader 1, Reader 2, reader 3) [DURATION 5days for each project]

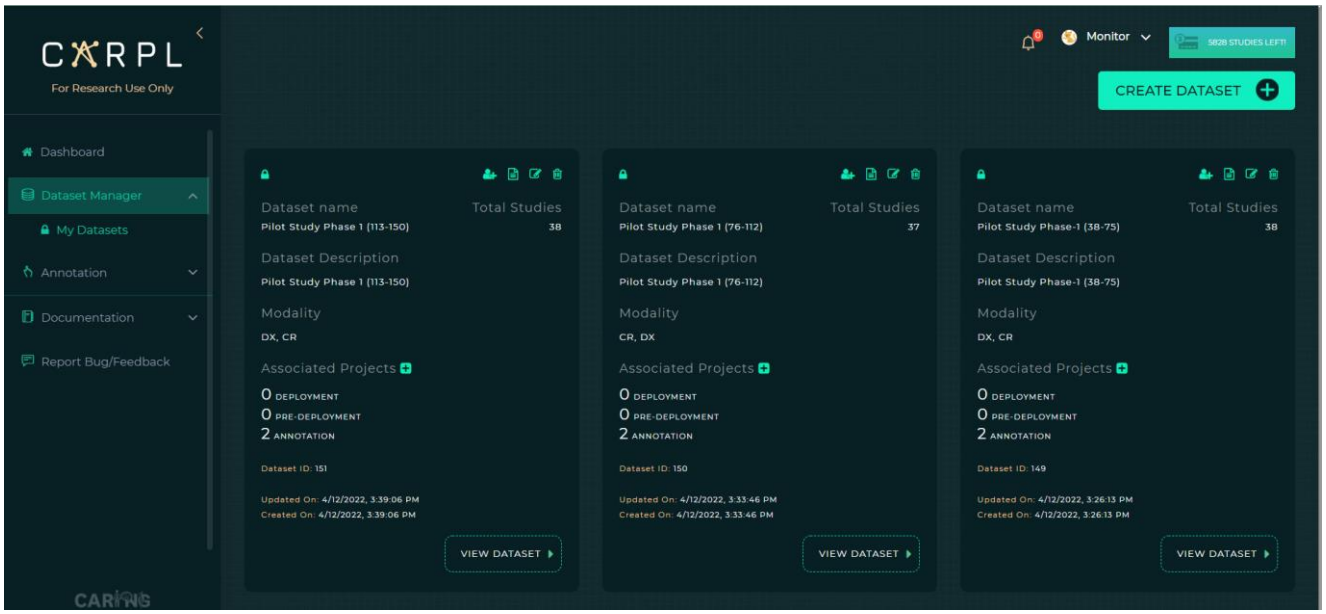


Reader Group 2 (Reader 4, Reader 5, Reader 6, Reader 7) [DURATION 5days each project]

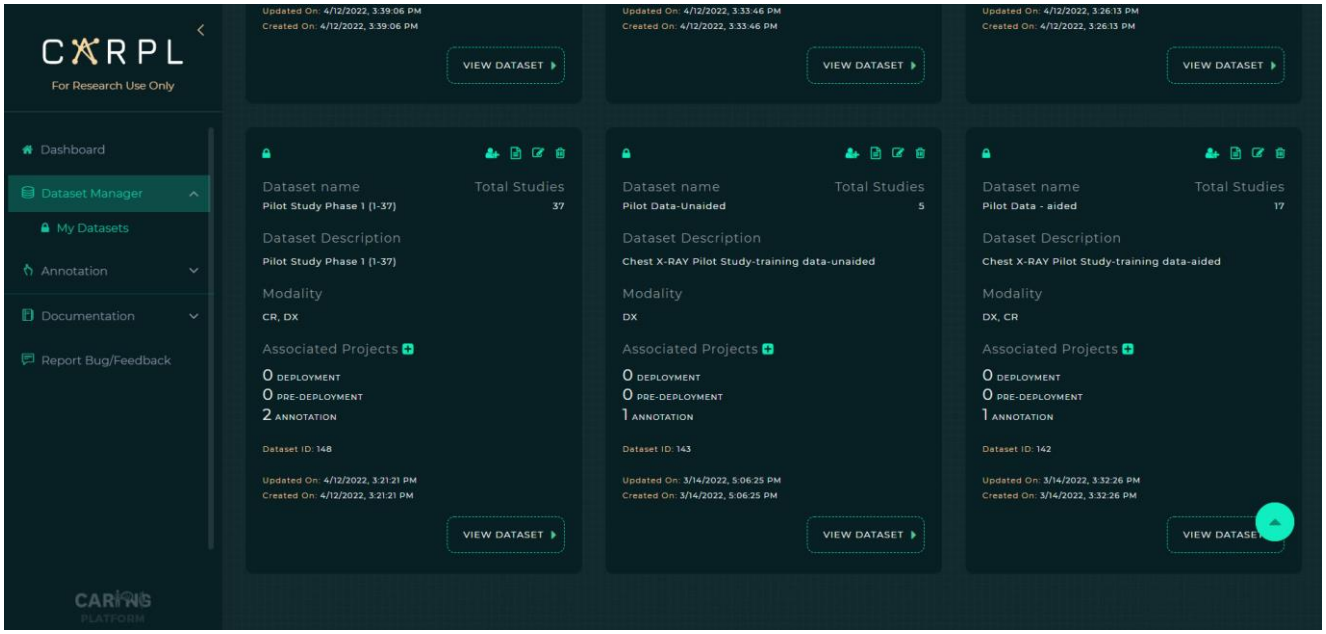




Dashboard provides summary reports and analysis of the application's data, trends of the signed in user

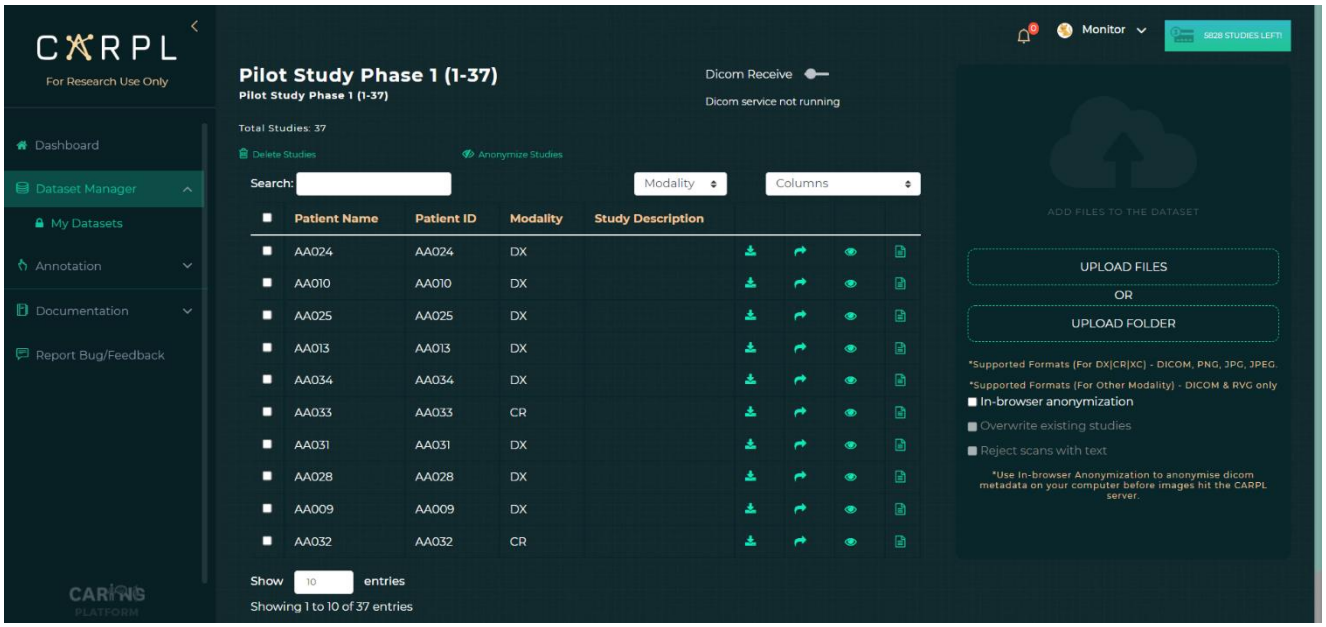


Datasets refers to the actual image data, either CT, MR, CR, DX, MG, US etc, on which an AI algorithm is to be tested. The user needs to create a Dataset, before project creation into which all of the data that the algorithm is to be tested on, is loaded. CARPL platform has the ability to anonymize data (using HIPAA compliant methods) while uploading. The user also has the ability to add and remove data from datasets after they are created. CARPL's SDK provides programmatic REST-APIs to create datasets and add or remove cases from existing datasets.



CARPL provides two types of datasets

- **My Datasets i.e., Private datasets:** My datasets contain datasets created by logged in user (in this case its the private dataset that was curated, cleaned and uploaded by me on to the platform)
- **Public datasets:** Public datasets contain datasets marked as public by CARING team or users.

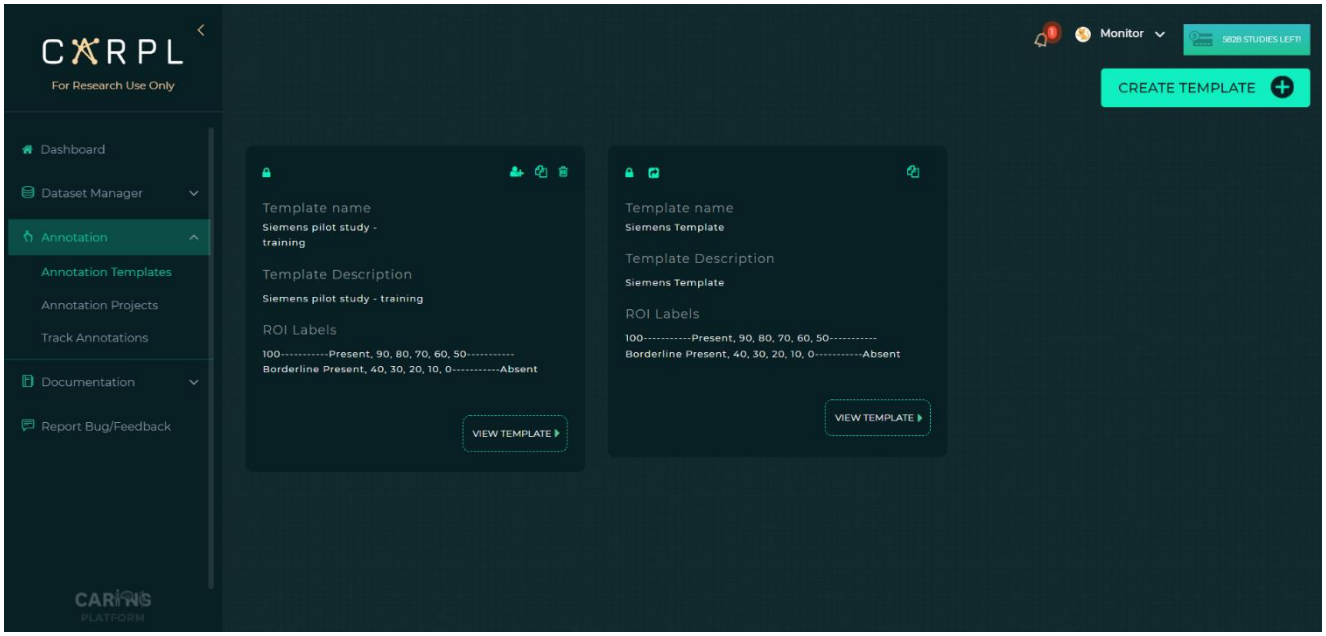


CARPL Web UI to Upload Dataset

1. User has uploaded files / folders to the dataset by clicking on the “Upload DICOM files

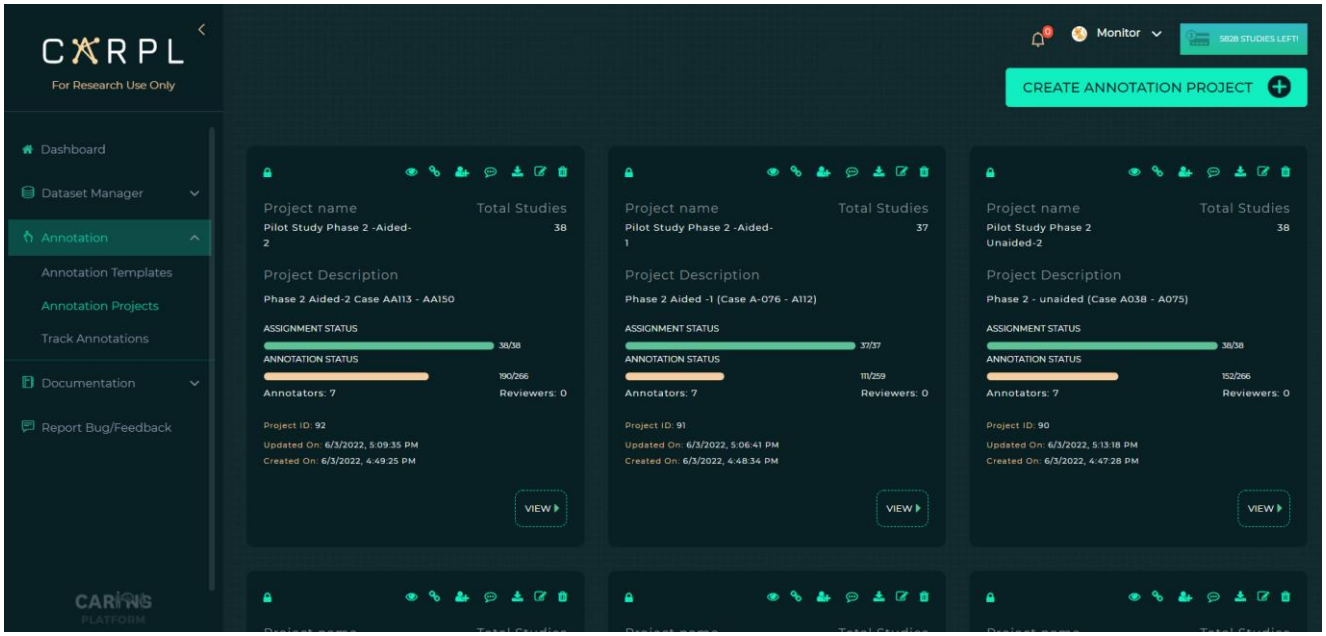
/ Upload DICOM folders”

2. After selecting the images , select “START UPLOAD” to initiate the upload process.
3. Only selected modality images are allowed if selected during “CREATE DATASET”.
4. In-browser anonymization to de-identify studies at your end.
5. System will provide a mapping csv file with actual studyid / patientid and anonymized studyid / patientid for reference.
6. User can see upload progress bar.
7. After upload user can visualize the status of the upload i.e, success, Failure, Duplicate and Invalid DICOM.



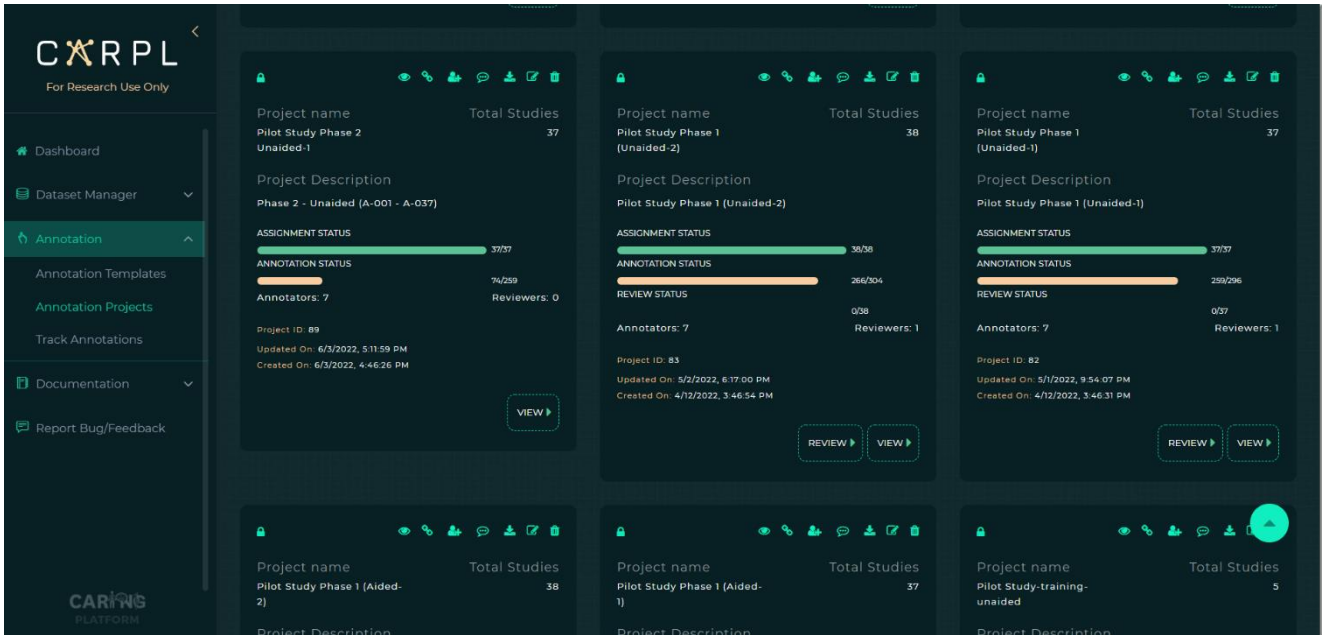
Feedback Template Created as per Requirements

- Click on "Annotation - Annotation Template" from the left panel
- Select "Create Template" from the top right corner
- Provide "Template Name, Template Description, and ROI Labels "
- ROI Labels can be selected from the dropdown menu or can be created.
- Drag elements from "Form elements" boxes and drop it in the form builder box
- User can create a copy of a form element and edit according to the requirement.
- Edit the "Form elements" if required.
- User can select "Required" to mark mandatory.
- "Preview" to review the template before saving the template
- "Save Template" to save the annotation template



Annotation projects created for different phases of study

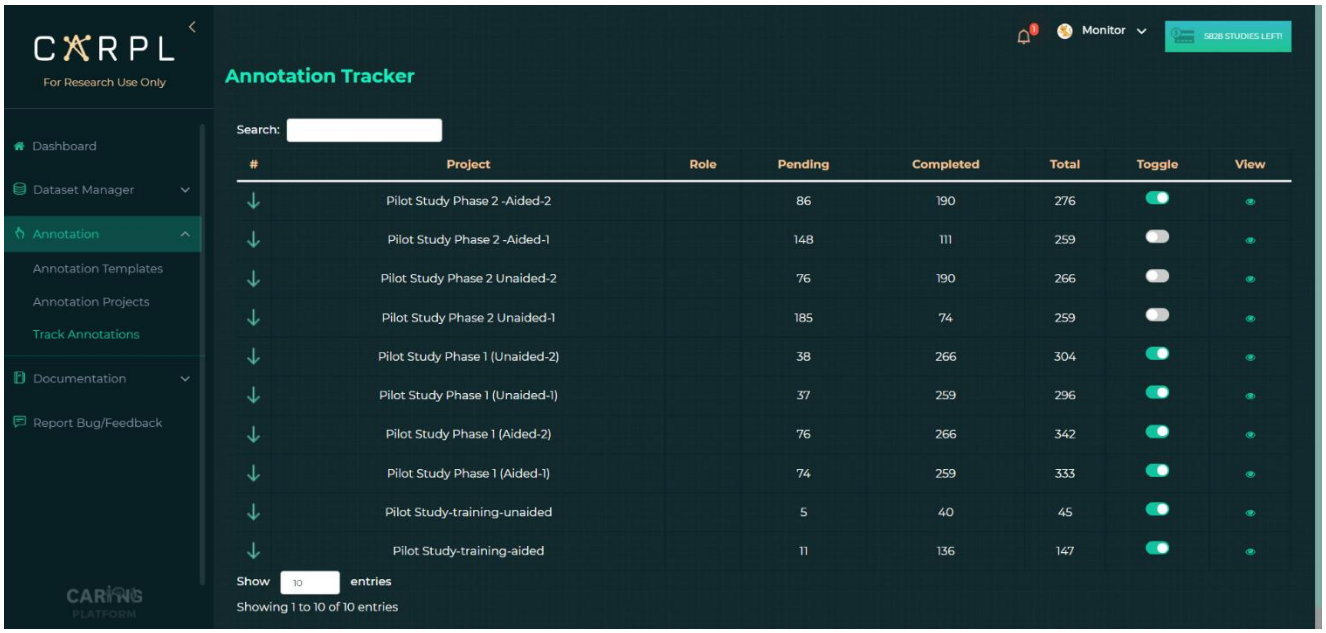
 Click on "**Create Annotation Project**" in the annotation platform
 Provide "**Project Name**", "**Description**" and "**Select Annotation Template”** and "**Select Algorithm**”
 Select "**Proceed**" then select desired "**Dataset**" from the datasets drop down
 Select "**Proceed**" to create an Annotation Project
 Annotation project will be created and user can see the newly created project in the Annotation summary Panel



Assigning of projects to different annotators

 Select studies and then click "**Assign Annotator** ", to assign annotator(s). Write email ids of the

annotators click "**assign**".
 The annotators will be notified via email.



Keeping the track of annotations as per study protocol

Experiments and Results

In total, 150 anonymized PA-view chest X-ray images with DICOM format were uploaded to the CARPL platform. One classification label -**Pulmonary lesions** (pulmonary nodules < 3cm and masses >= 3cm) was determined and assigned to the project. A case mix of true positive and true negative cases was included.

The users followed the reading workflow that involved:

- Using the entire likelihood scale
- Using the scale consistently for aided and unaided reading
- First report all findings (tightly fitting bounding box and finding level likelihood score) and then assess case level

The following findings were reported

- All nodules- calcified or not
- Findings were marked as per clinical practice (same level of sensditivity)

To suggest a clear analysis method, we only concentrated on one critical label with a clinically high value (i.e. pulmonary lesion).

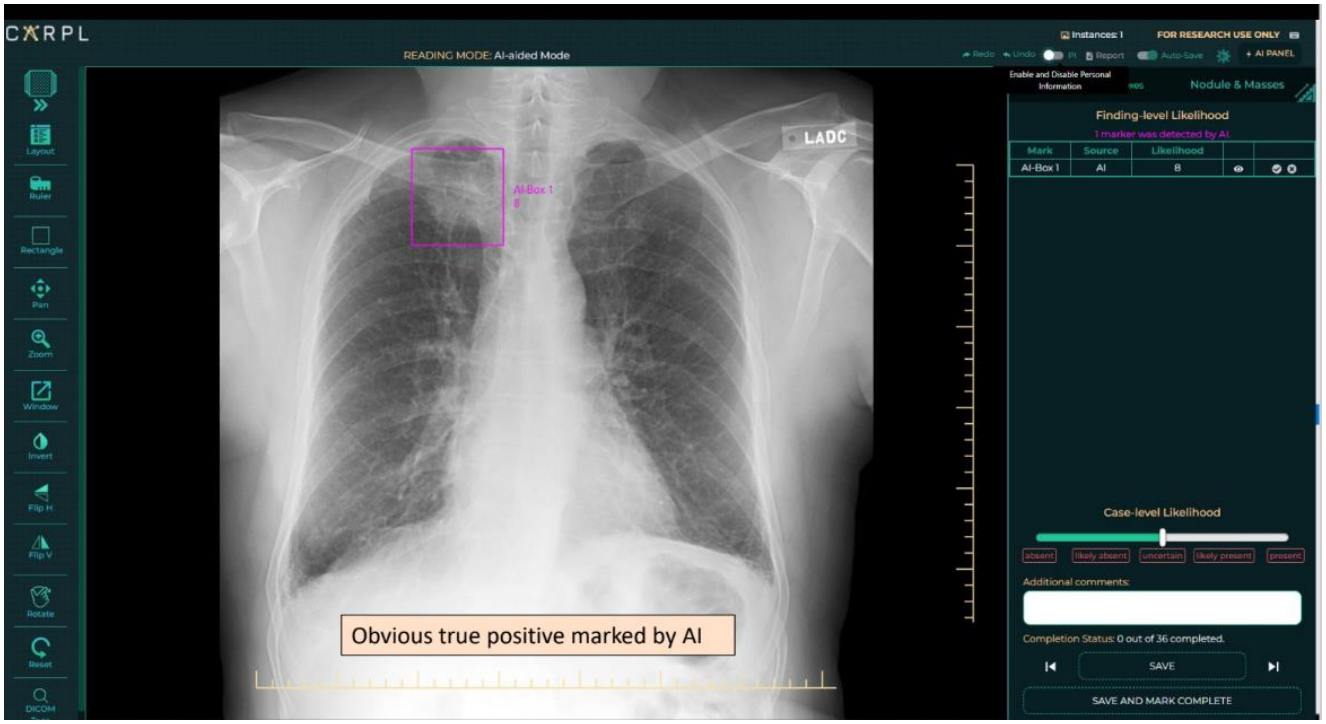
The CARPL platform was utilized to perform the following tasks as per study protocol:

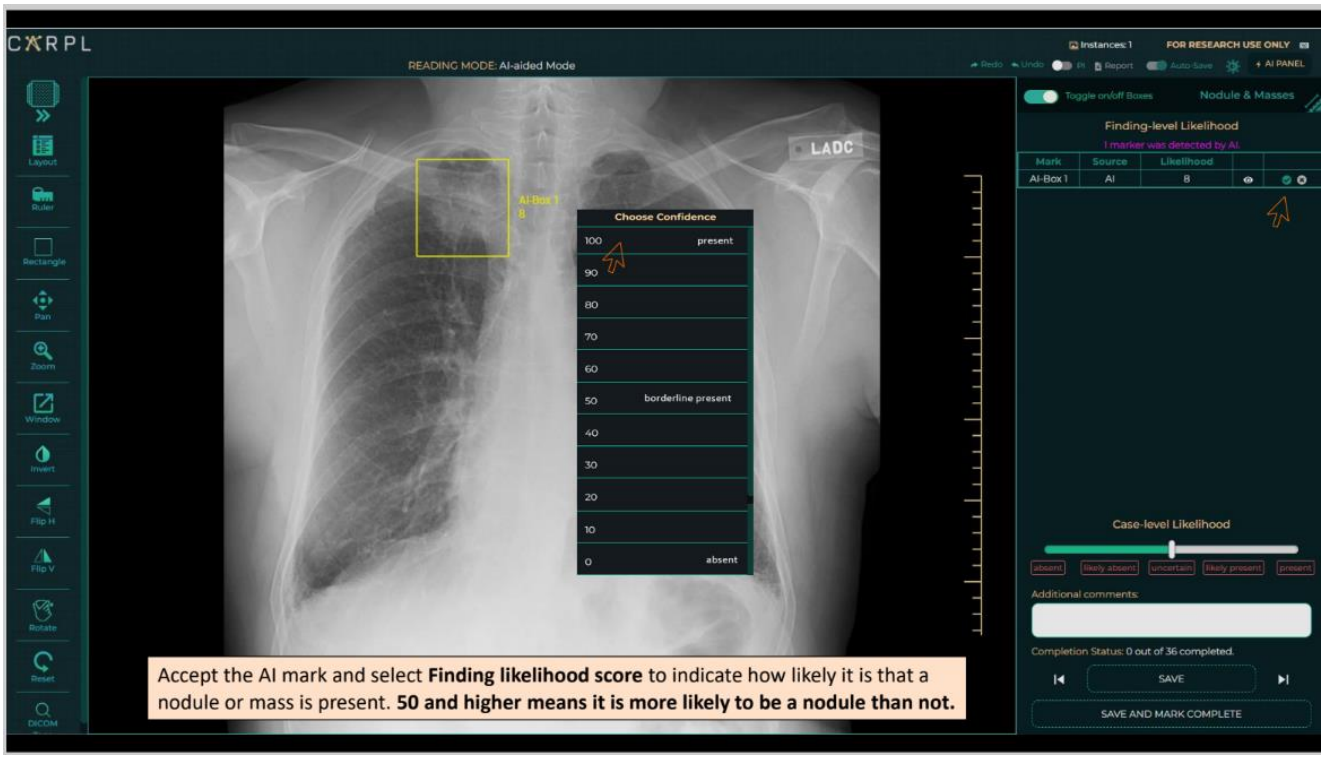
- Successful upload of data with anonymization
- Creation of annotation projects linked to annotation projects that were successfully assigned to 7 users (radiologists)
- Tracking the annotations and assigning projects as per protocol to aid in completion of study as per timelines

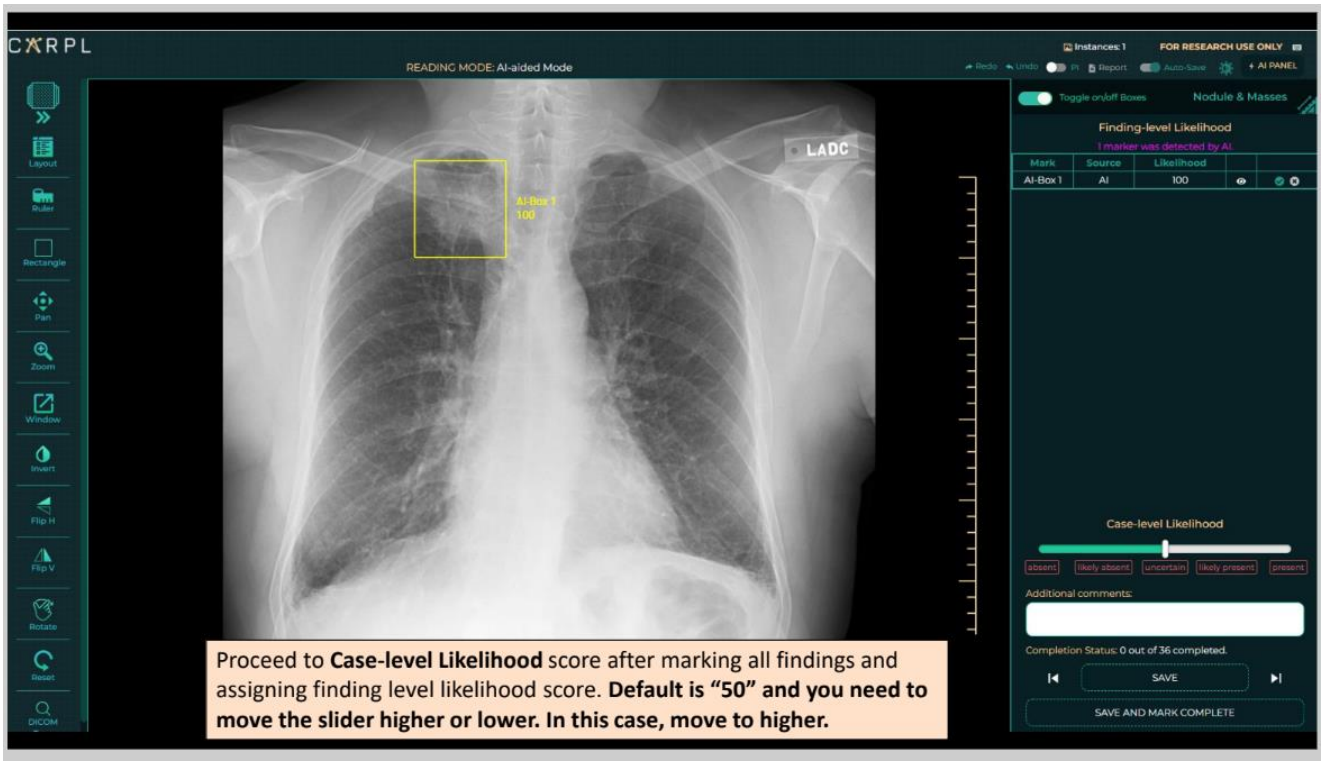
Below are some of the screenshots of how CARPL platform was helpful in conducting the study taking two examples:

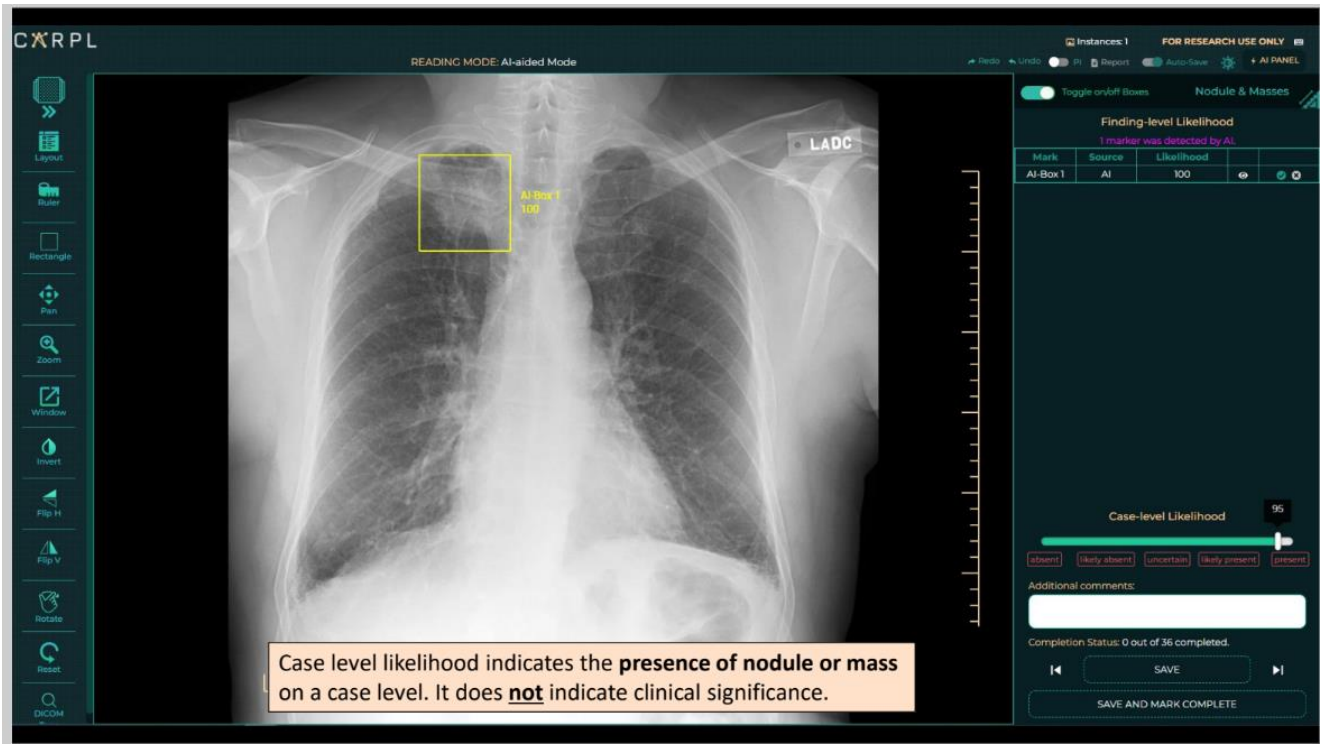
1. True positive
2. False positive

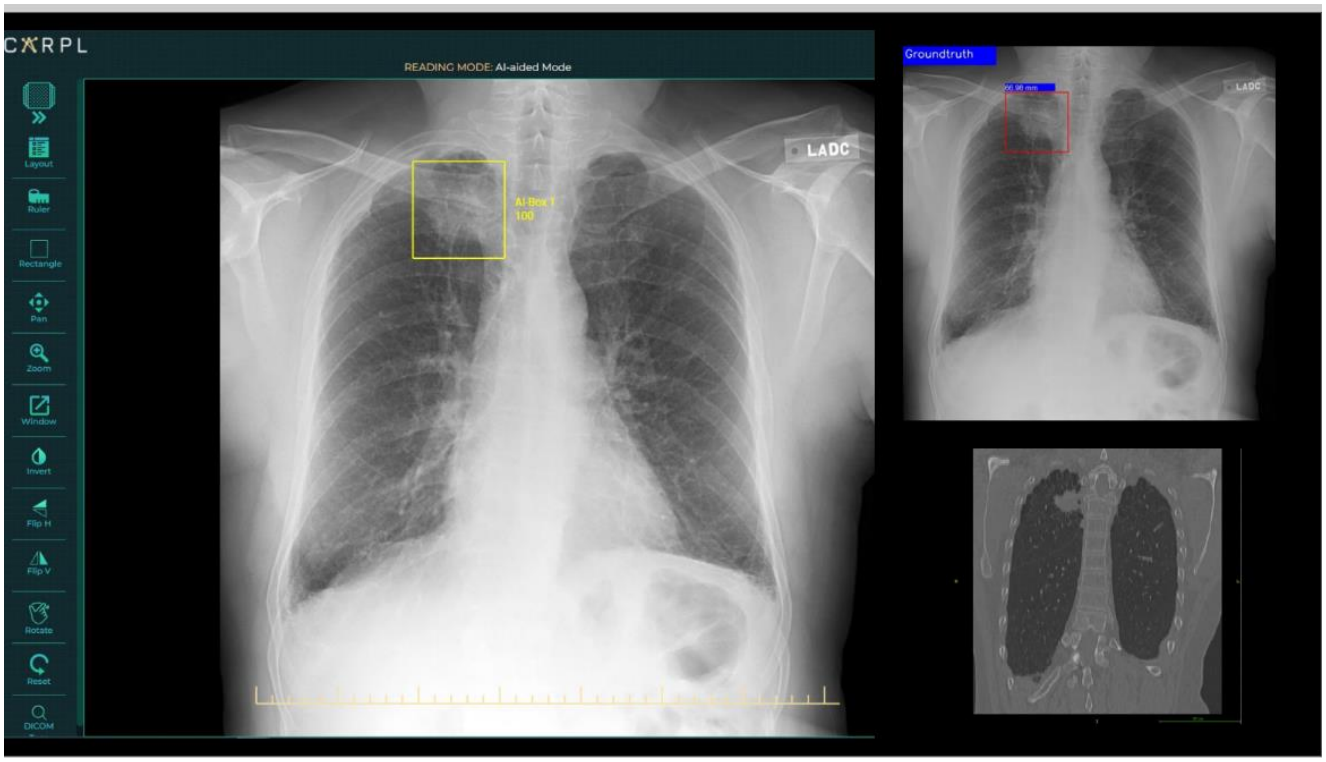
Reading assistance in true positive cases marked by AI



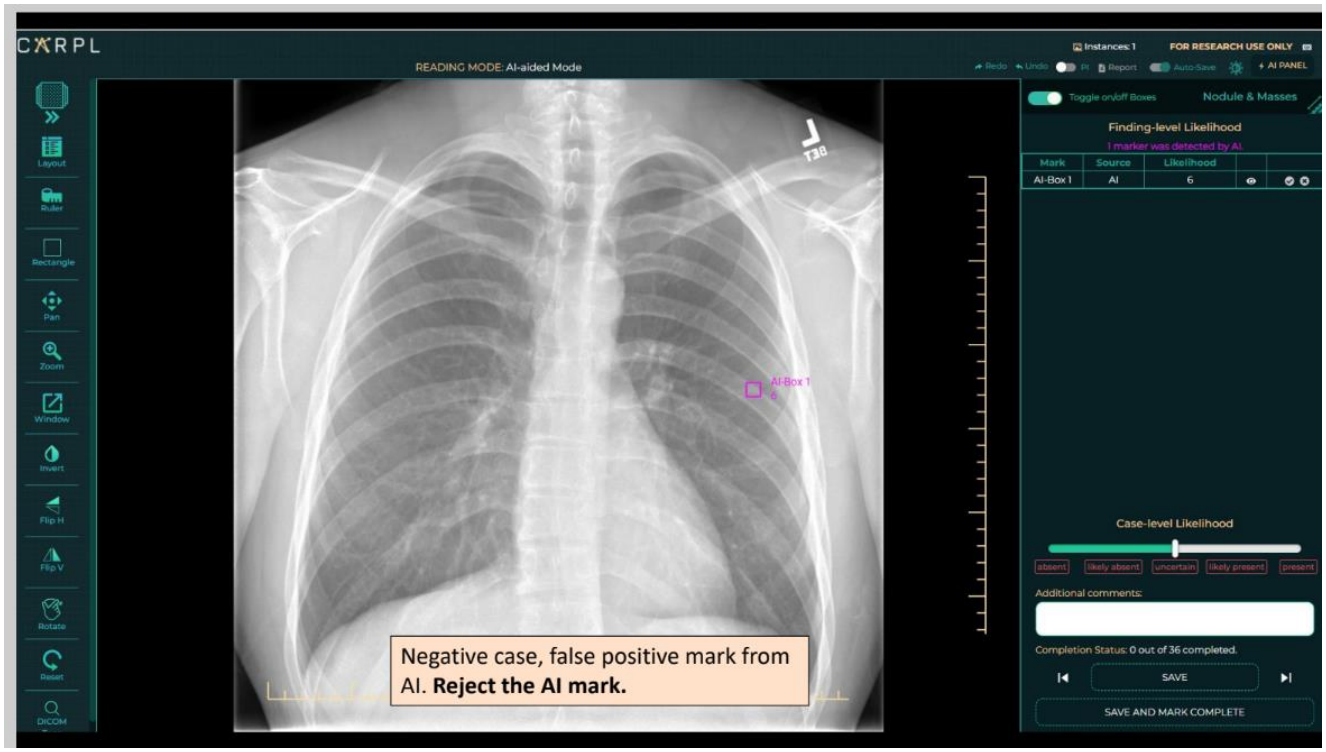


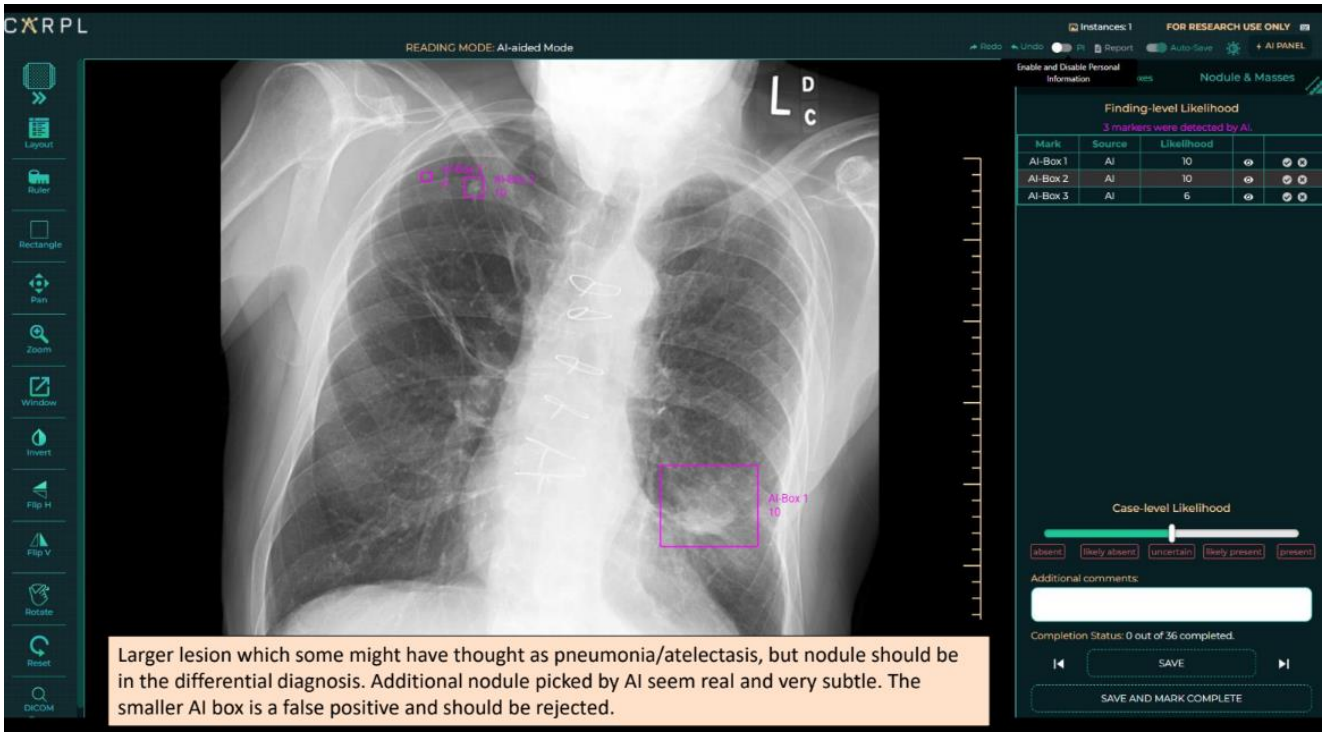

CXRPL
READING MODE: AI-aided Mode
Instances: 1
FOR RESEARCH USE ONLY
Nodule & Masses
Finding-level Likelihood
1 marker was detected by AI.
Mark
Source
Likelihood
AI-Box 1
AI
100
LADC
AI-Box 1
100
Case-level Likelihood
absent
likely absent
uncertain
likely present
present
Additional comments:
Completion Status: 0 out of 36 completed.
SAVE
SAVE AND MARK COMPLETE
Proceed to **Case-level Likelihood** score after marking all findings and assigning finding level likelihood score. **Default is "50" and you need to move the slider higher or lower. In this case, move to higher.**


CXRPL
READING MODE: AI-aided Mode
Instances: 1
FOR RESEARCH USE ONLY
Nodule & Masses
Finding-level Likelihood
1 marker was detected by AI.
Mark
Source
Likelihood
AI-Box 1
AI
100
LADC
AI-Box 1
100
Case-level Likelihood
95
absent
likely absent
uncertain
likely present
present
Additional comments:
Completion Status: 0 out of 36 completed.
SAVE
SAVE AND MARK COMPLETE
Case level likelihood indicates the **presence of nodule or mass** on a case level. It does **not** indicate clinical significance.

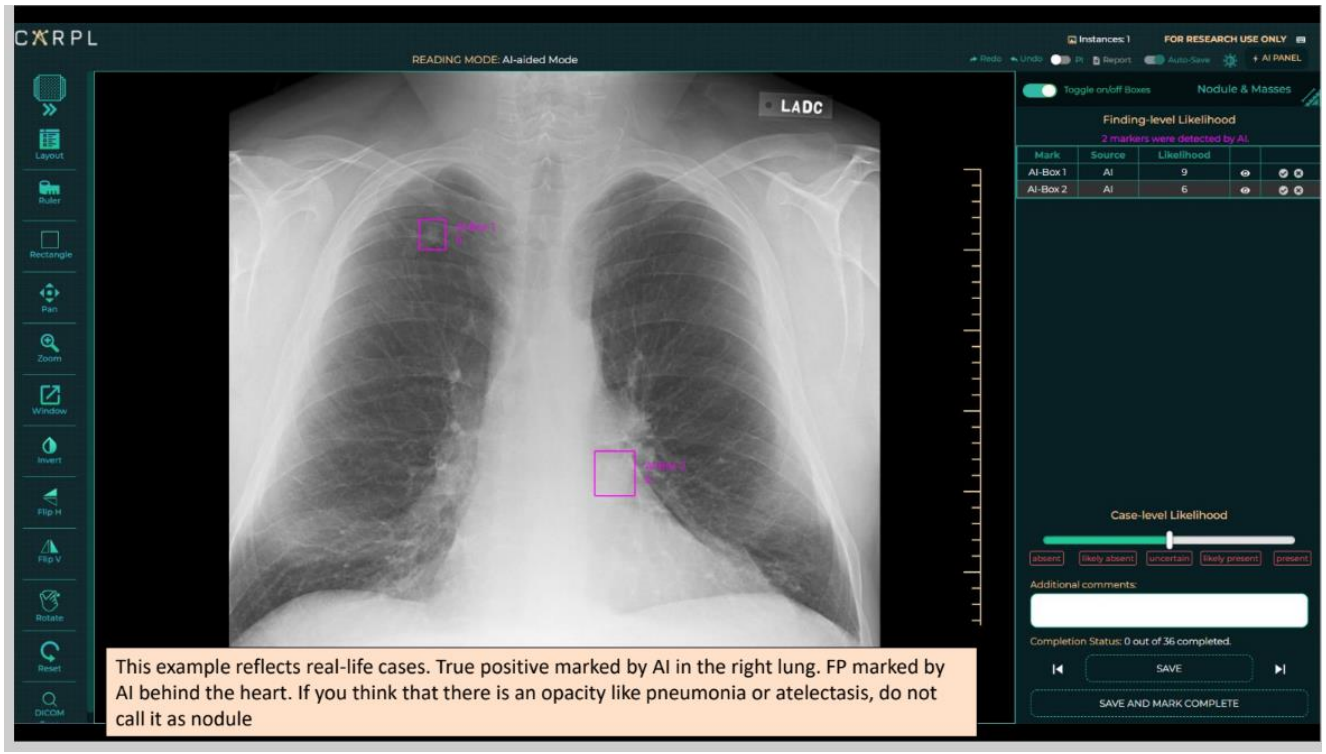


Reading assistance in false positive cases marked by AI

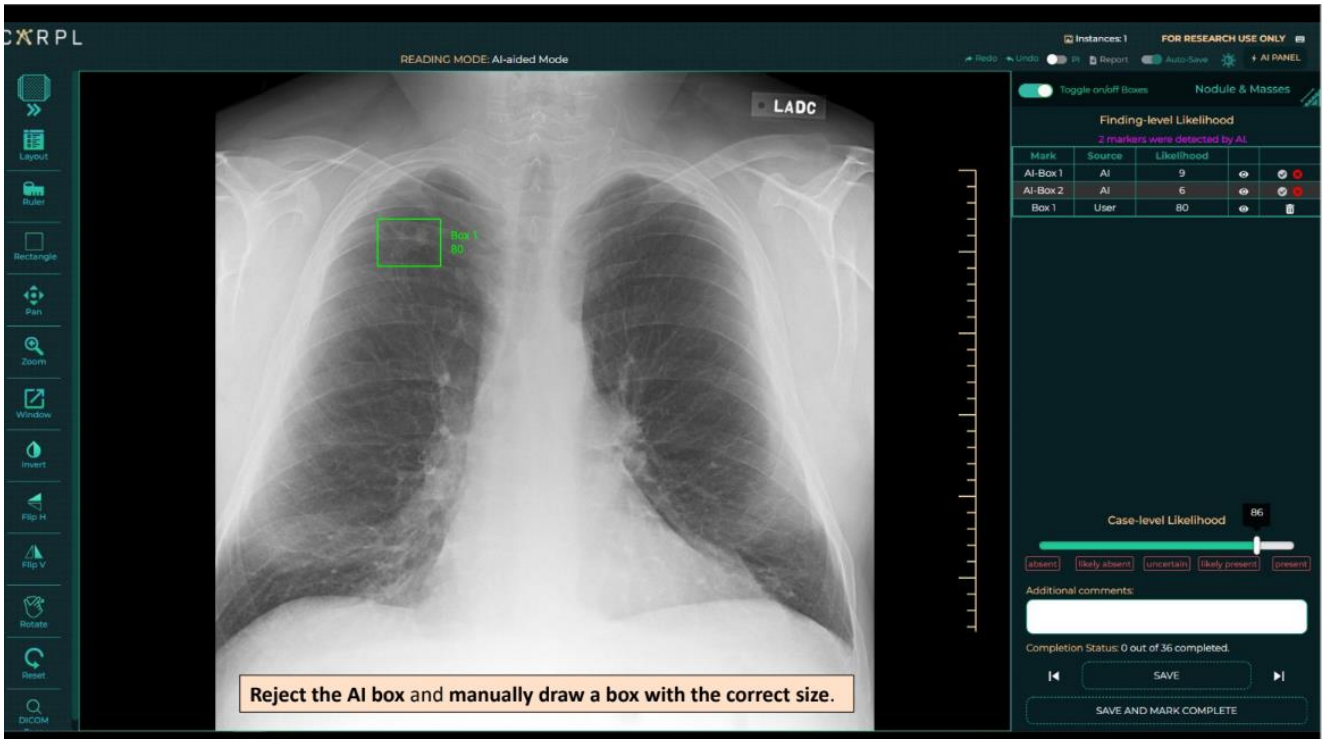




Larger lesion which some might have thought as pneumonia/atelectasis, but nodule should be in the differential diagnosis. Additional nodule picked by AI seem real and very subtle. The smaller AI box is a false positive and should be rejected.



This example reflects real-life cases. True positive marked by AI in the right lung. FP marked by AI behind the heart. If you think that there is an opacity like pneumonia or atelectasis, do not call it as nodule


READING MODE: AI-aided Mode
FOR RESEARCH USE ONLY
LADC
Box 1
80
Nodule & Masses
Finding-level Likelihood
2 markers were detected by AI.
Mark
Source
Likelihood
AI-Box 1
AI
9
AI-Box 2
AI
6
Box 1
User
80
Case-level Likelihood
86
absent
likely absent
uncertain
likely present
present
Additional comments:
Completion Status: 0 out of 36 completed.
SAVE
SAVE AND MARK COMPLETE
Reject the AI box and manually draw a box with the correct size.

Discussion

Medical imaging annotations require the knowledge of a qualified radiologist, and using Platform as a Service such as CARPL can be advantageous:

• It provides faster production of high-quality labelled datasets,
• It lowers the overall cost of getting annotations on huge datasets,
• Aid in faster development of machine learning or artificial intelligence for a variety of medical imaging jobs.

The platform could be used by researchers and commercial vendors to speed up the annotation and development of medical imaging datasets. Labelling for categorization and object identification activities, as well as data and project management tools, are already accessible options.

The usefulness of a platform as a service that is simple to apply on both a local and global scale is presented in this research study. CARPL platform is designed in such a way that its user-friendliness helps the users to utilize its features adequately for maximum benefit. Additionally, if required, we can also provide annotators with additional clinical information, such as radiological reports or patient history, in order to improve annotation accuracy.

Other created tools, such as Philbrick et alRIL-Contour's are often more task specialised. The authors demonstrated volumetric annotation tools, specifically image segmentation. They also featured presenting saliency maps to better identify model interference and leveraging locally generated AI models. Their method, however, is not web-based or synced, severely limiting the possibility for crowdsourcing announcements. In addition, instead of using the DICOM Standard, they employed the NifTI file format. Chen et al. introduced DeepLNAnno, a web-based system that integrates deep learning models into the platform for pre-annotation. However, their solution is dedicated solely to lung nodule annotation in CT examinations.

CARPL, on the other hand, aims to overcome prior research constraints by providing a powerful platform that can scale and add new functionality quickly by connecting different modules in the lifecycle of an artificial algorithm. CARPL was able to provide image upload security and annotation record modulation security without sacrificing user comfort.

CARPL presently has a few restrictions. For starters, picture segmentation techniques are not yet included within our platform. Alternative tools, such as 3D Slicer, are better suited to complicated picture segmentation, which most often needs a more complex workflow and many manual and/or semi-automatic segmentation techniques are in the works. Second, our platform currently lacks full support for volumetric images as well as DICOM-SEG and DICOM-SR non-image DICOM instances. Finally, while CARPL allows users to upload DICOM and non-DICOM (e.g. JPG) picture files, the radiology research community generally uses other fundamental imaging formats such as NIfTI (especially in the neuroimaging sector) or NRRD (Nearly Raw Raster Data).

Conclusion

Researchers can swiftly assess a dataset's worth and avoid data contamination due to incorrect annotation. By using CARPL platform, the client was able to conduct a pilot study that was a “dry-run” for pivotal study intended for FDA clearance. Using CARPL’s PaaS features, the client was able to assess whether AI can help readers read more accurately.

AI supports the radiologist review,but is something that cannot be totally relied upon. AI has demonstrated reader improvement in studies with previous algorithms and has helped radiologists detect nodules/masses with higher accuracy.

The confidence score feature on our platform helped the radiologists decide on the confidence of finding presence rather than its measure of actionability or malignancy. The deliberate evaluation of AI marks is important and it can be achieved best with fixed pattern like if you start reading with AI it is likely to reduce interpretation time and if you End with AI it provides higher sensitivity.

The impact of CARPL platform in data exchanges and annotation that are useful to conduct a clinical trial will be a fascinating research issue. CARPL is a medical imaging-specific collaborative annotation platform that effectively helps the user do annotations and gives indications for assessing the value of data and annotators' efforts.

References

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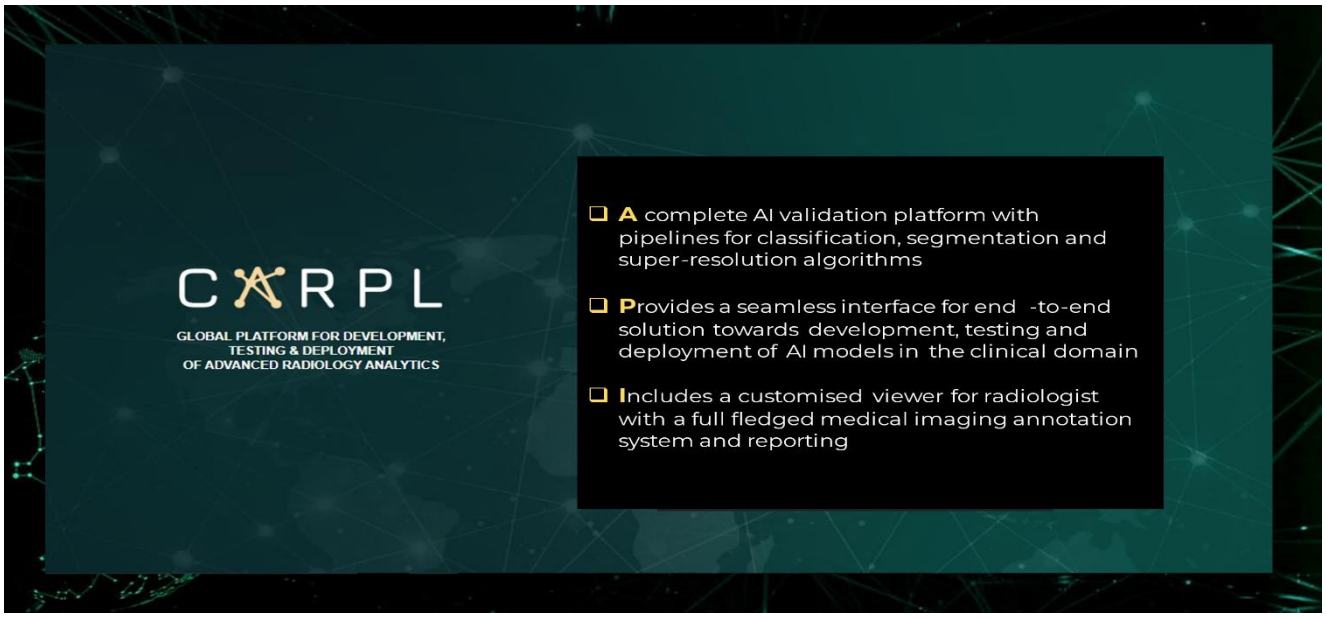
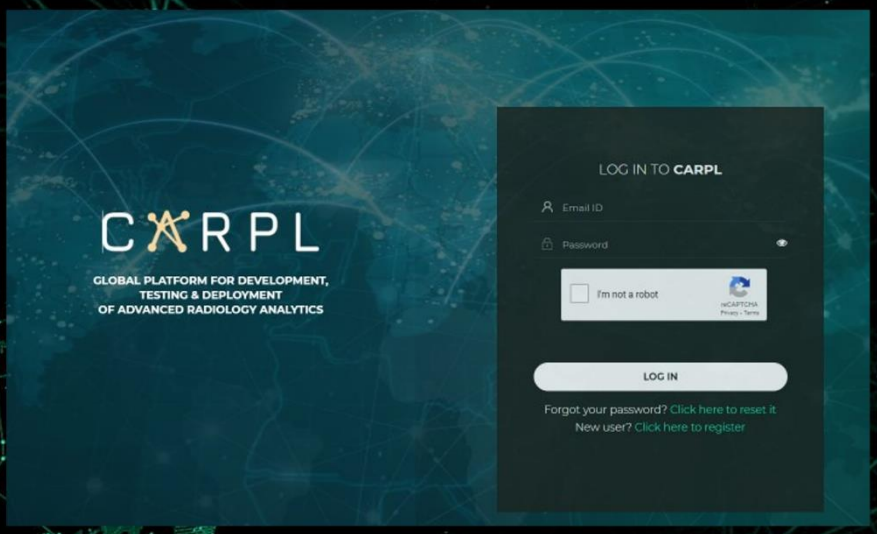
- Chen, Sihang & Guo, Jixiang & Wang, Chengdi & Xu, Xiuyuan & Yi, Zhang & Li, Weimin. (2019). DeepLNAnno: a Web-Based Lung Nodules Annotating System for CT Images. Journal of Medical Systems. 43. 10.1007/s10916-019-1258-9

Annexures

CARPL PLATFORM- OVERVIEW



CARPL Login:



- Login by using registered email ID and password
- Forgot password to reset the password
- CAPTCHA- A security measure before logging - In

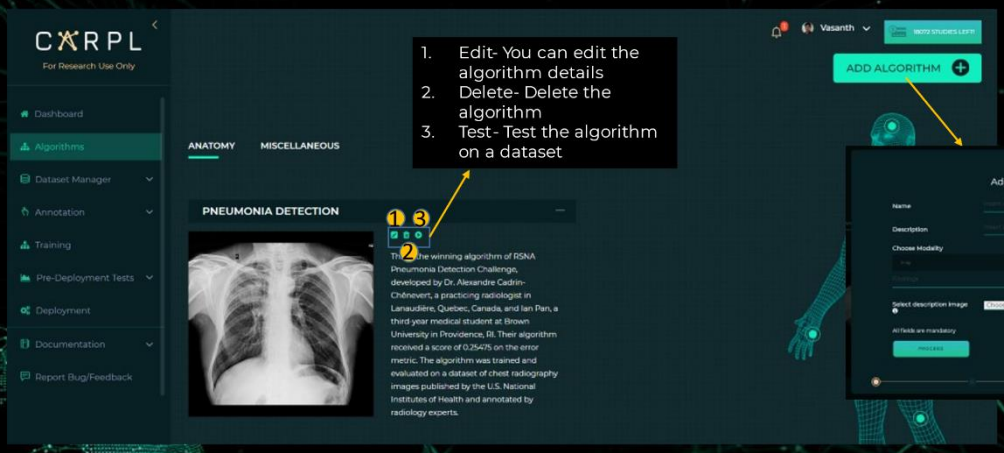
CARPL

CARPL Dashboard:

- Dashboard will present a summary report of dataset and project.

CARPL

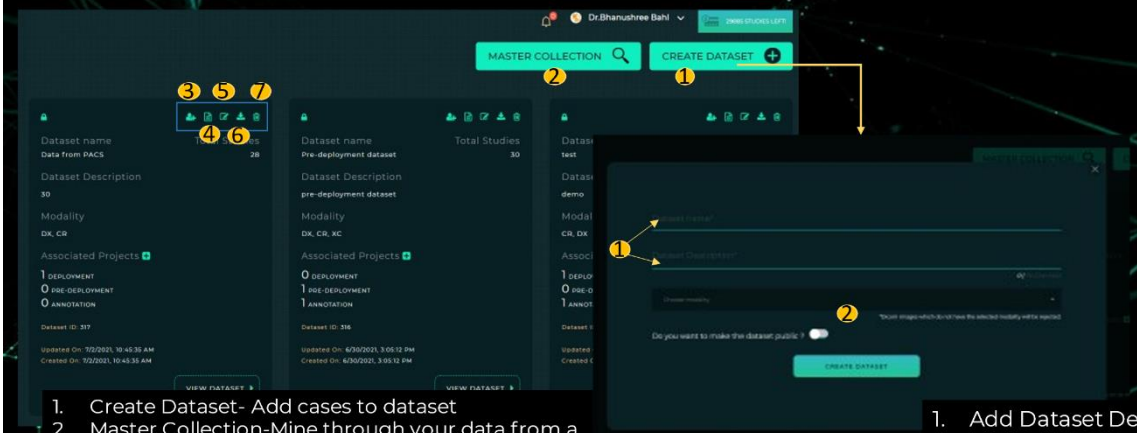
Algorithm:



- Algorithm section will show complete list of algorithms available in CRAPL and also an brief introduction about the each of them
- Add Algorithm: Integrate any API algorithm from your account directly

CRPL

Dataset Manager: My Datasets

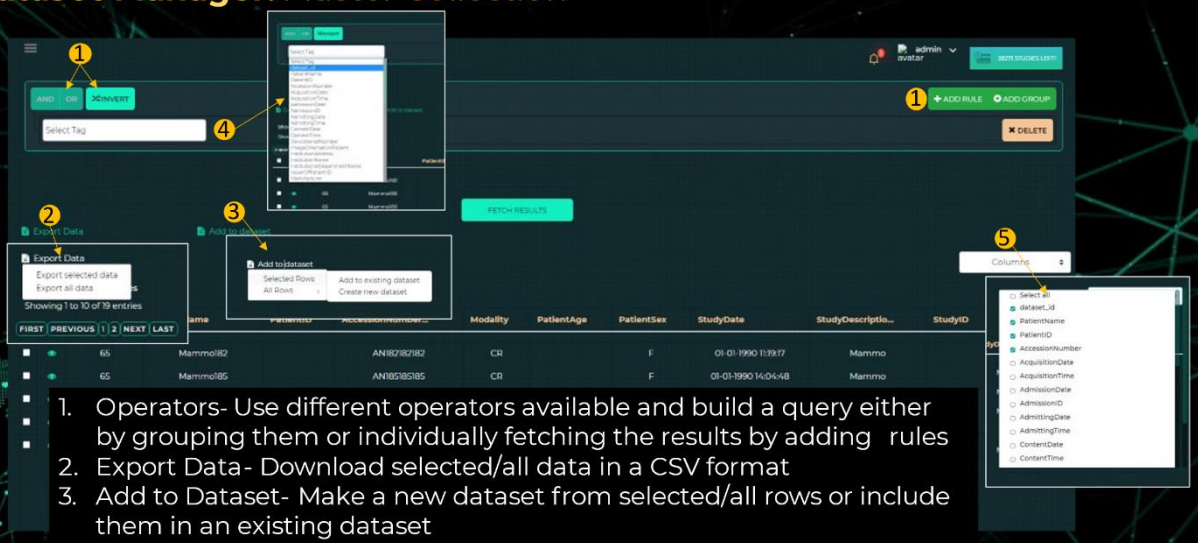


1. Create Dataset- Add cases to dataset
2. Master Collection-Mine through your data from a single master collection and make subsets from it
3. Share Dataset- Share dataset with other users
4. Add Reports-Add textual/metadata to the dataset
5. Edit Dataset- Edit dataset details
6. Download Dataset
7. Delete Dataset- Delete unwanted datasets

1. Add Dataset Details - Name and Description
2. Select a modality or leave blank for multiple modalities

CRPL

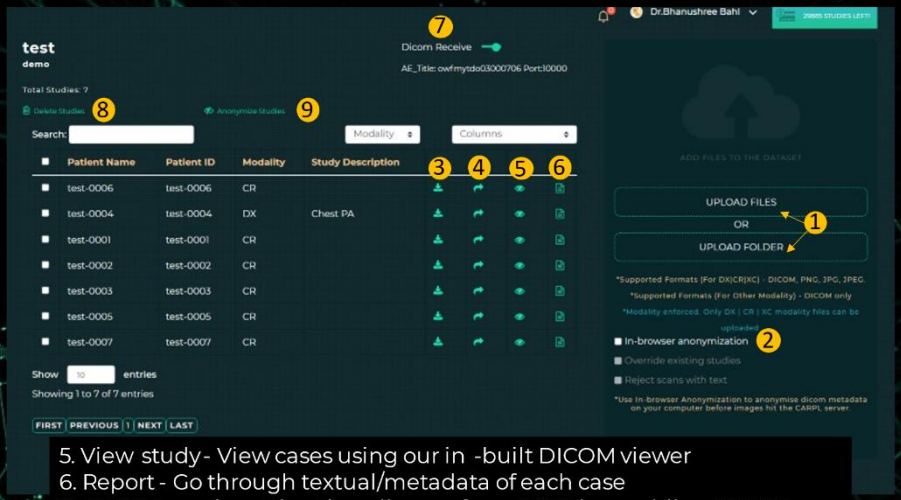
Dataset Manager: Master Collection



1. Operators- Use different operators available and build a query either by grouping them or individually fetching the results by adding rules
2. Export Data- Download selected/all data in a CSV format
3. Add to Dataset- Make a new dataset from selected/all rows or include them in an existing dataset
4. Select Tag- Select attributes available to build a query
5. Columns- Select visible attributes

CARPL

Dataset Manager: My Datasets

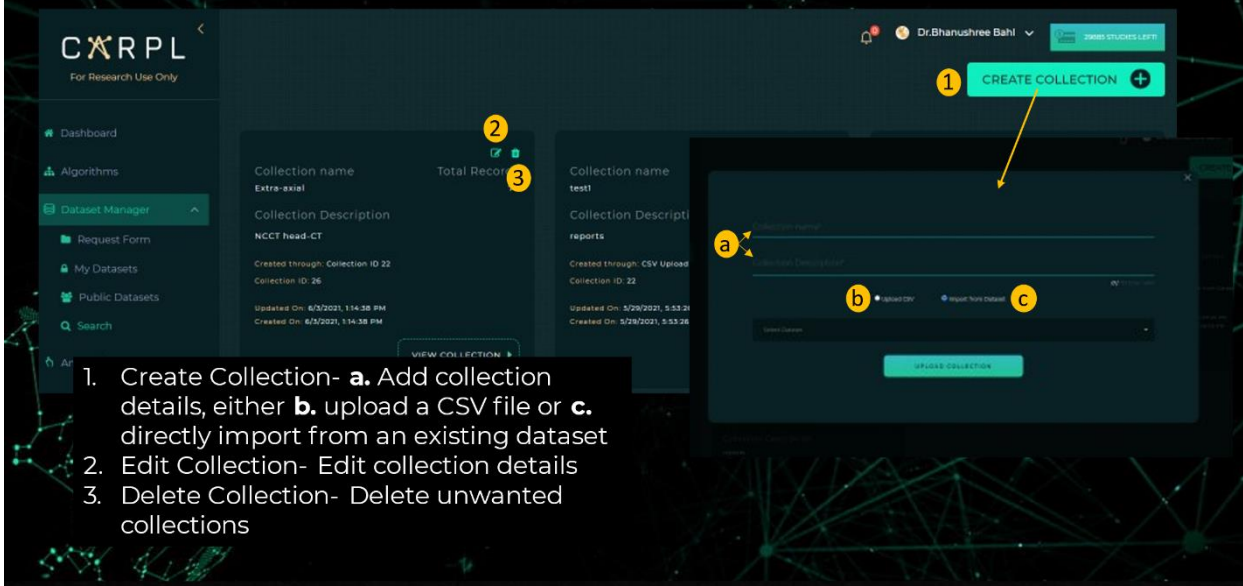


1. Upload Files/Folder - Upload cases as a single file or a folder
2. In-browser Anonymization - Anonymize cases on the fly while uploading cases using our in-browser anonymization tool
3. Download study - Download individual cases
4. Share study - Share individual cases with other users

5. View study - View cases using our in-built DICOM viewer
6. Report - Go through textual/metadata of each case
7. DICOM receive - Directly pull cases from PACS by enabling DICOM receive, which gives a AE title and port number for that IP address
8. Delete studies - Delete unwanted cases
9. Anonymize studies - Anonymize individual cases

CARPL

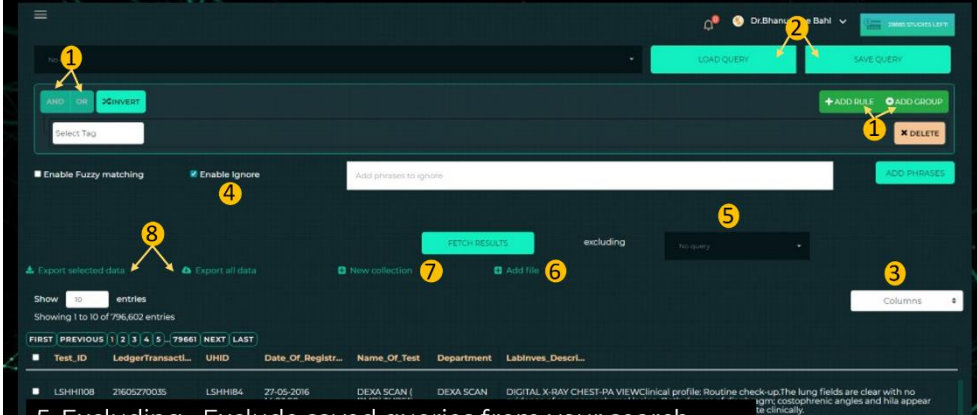
Dataset Manager: Search



1. Create Collection- **a.** Add collection details, either **b.** upload a CSV file or **c.** directly import from an existing dataset
2. Edit Collection- Edit collection details
3. Delete Collection- Delete unwanted collections

CARPL

Dataset Manager: Search



1. Operators- Use different operators available and build a query either by grouping them or individually fetching the results by adding rules
2. Save/Load Query- Save the build query to an existing one or a new one, load previously saved queries
3. Columns- Select visible attributes
4. Enable Ignore- Ignore phrases from your search

5. Excluding- Exclude saved queries from your search
6. Add file- Add more data to existing collection
7. New collection - Create a new collection out of the selected data
8. Export selected/all data- Download selected/all data

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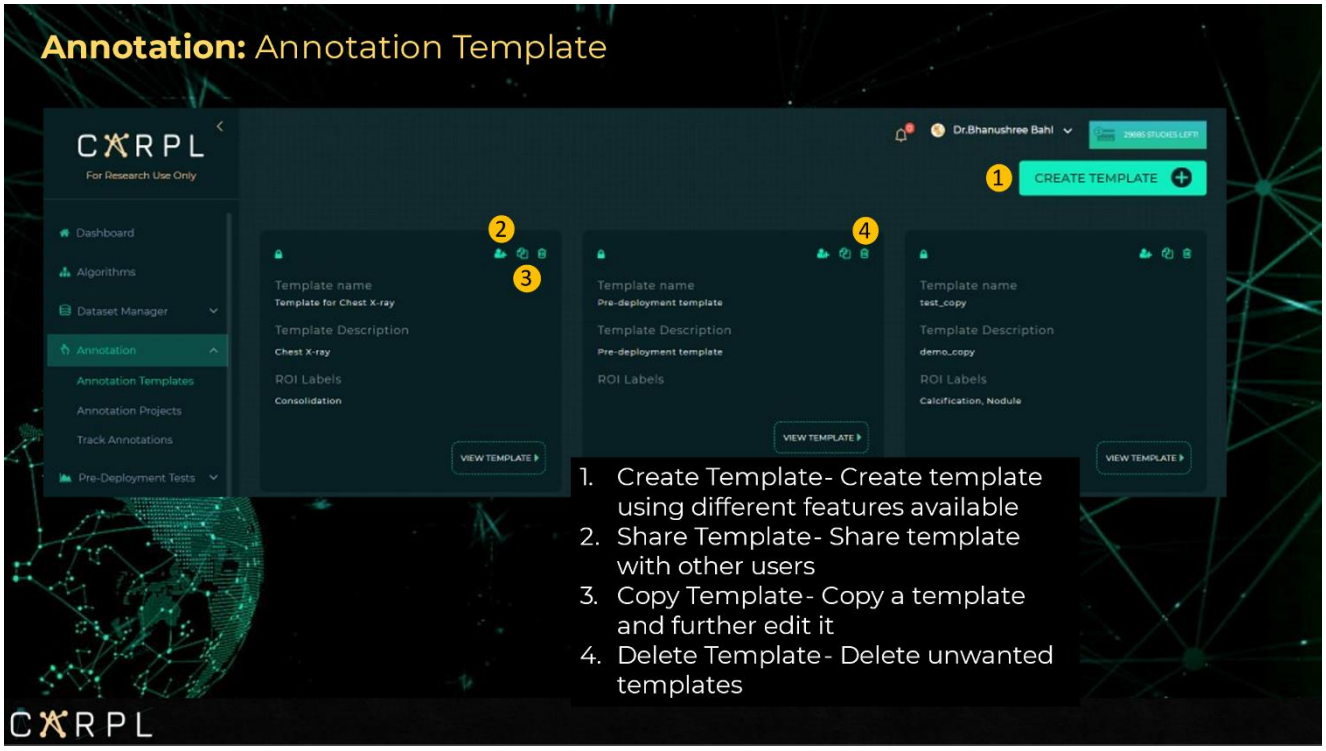
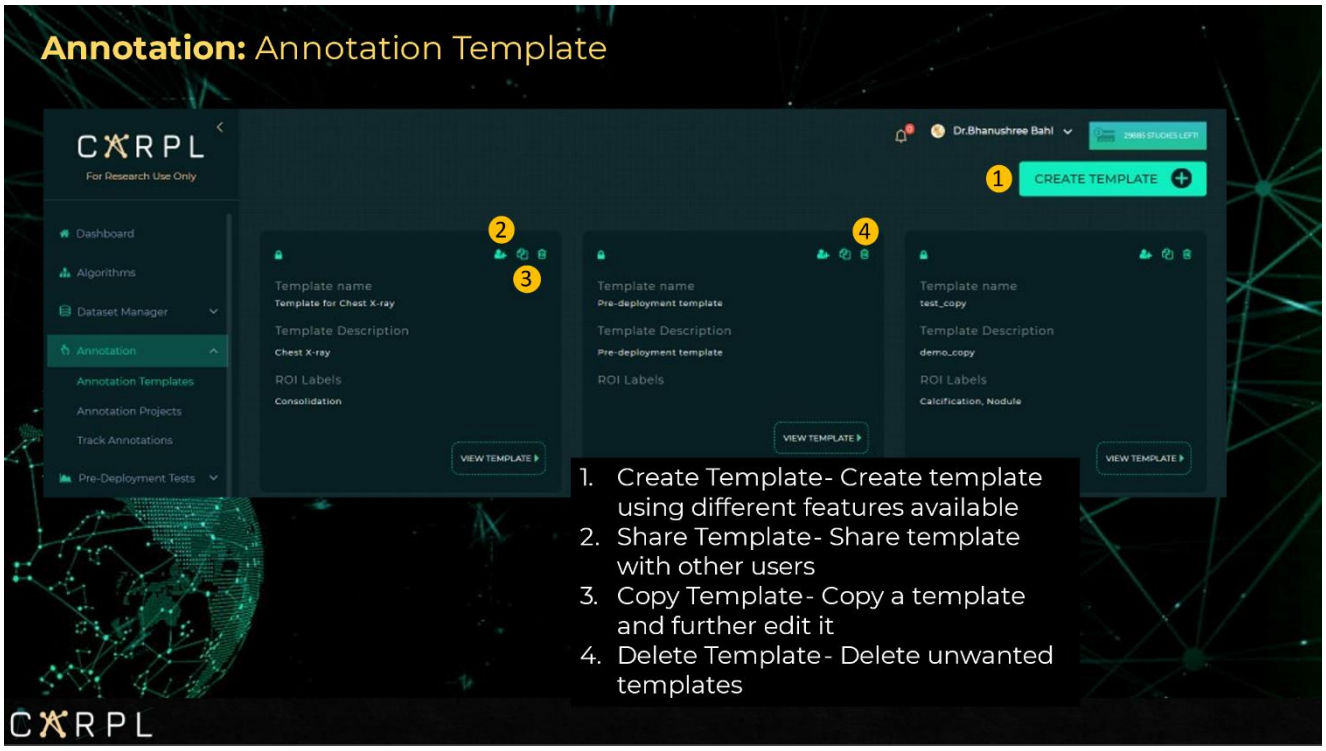
Annotation: Annotation Template



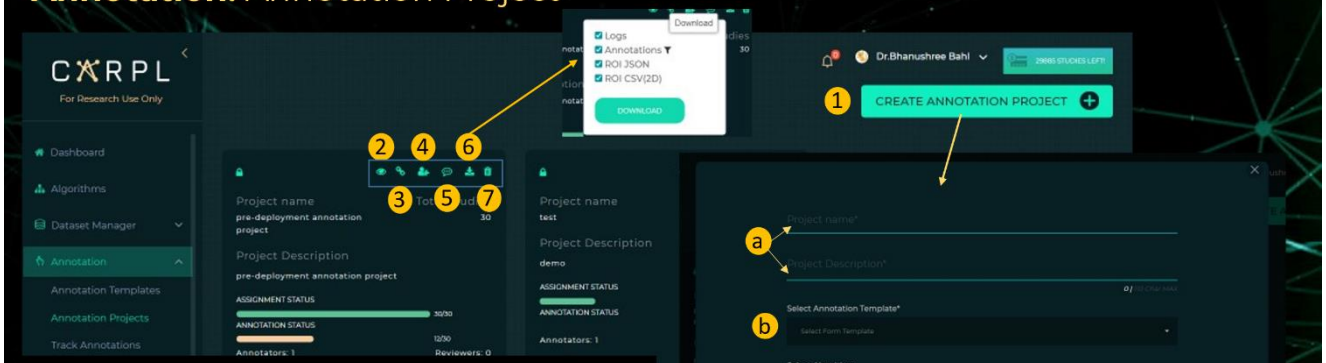
1. Create Template- Create template using different features available
2. Share Template- Share template with other users
3. Copy Template- Copy a template and further edit it
4. Delete Template- Delete unwanted templates

Annotation: Annotation Template



1. Create Template- Create template using different features available
2. Share Template- Share template with other users
3. Copy Template- Copy a template and further edit it
4. Delete Template- Delete unwanted templates

Annotation: Annotation Project



1. Create Annotation project
2. View Template - View linked template
3. Link to pre-deployment project - Link annotation project to pre -deployment project
4. Assign annotations- Assign annotation cases to all/selected studies
5. Add reviewer - Add reviewer to all/selected cases
6. Download - Download logs, annotations, ROI in JSON format or in CSV format
7. Delete- Delete unwanted annotation projects

a. Add Project details
b. Select an Annotation template
c. User can also select an algorithm

Annotation: Annotation Project

1. Assign Annotator - Assign annotators to selected/all cases
2. Assign to myself- Assign cases to self for annotations either all or selected cases
3. Auto-assign - Auto-assign cases to users, as new cases will get loaded onto the project, directly the cases will be assigned to linked user
4. Remove - Remove annotators either from all/selected cases
5. Assigned/unassigned- View cases according to assigned or non -assigned cases

Annotation: Track Annotations

- Track Annotations- Keep a track of all the annotation project and their statuses

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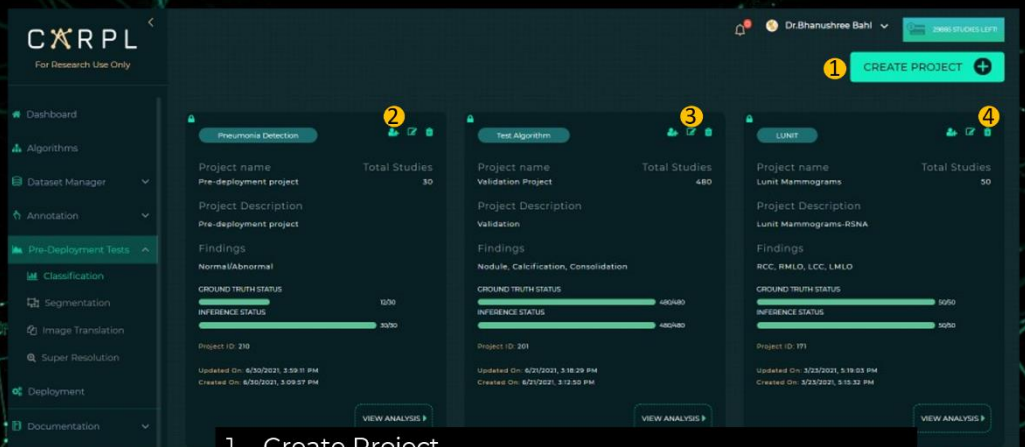
Pre-Deployment Test: Classification



1. Create Project
2. Share Project- Share the projects with other users
3. Edit Project- Edit validation details
4. Delete Project- Delete unwanted validation projects

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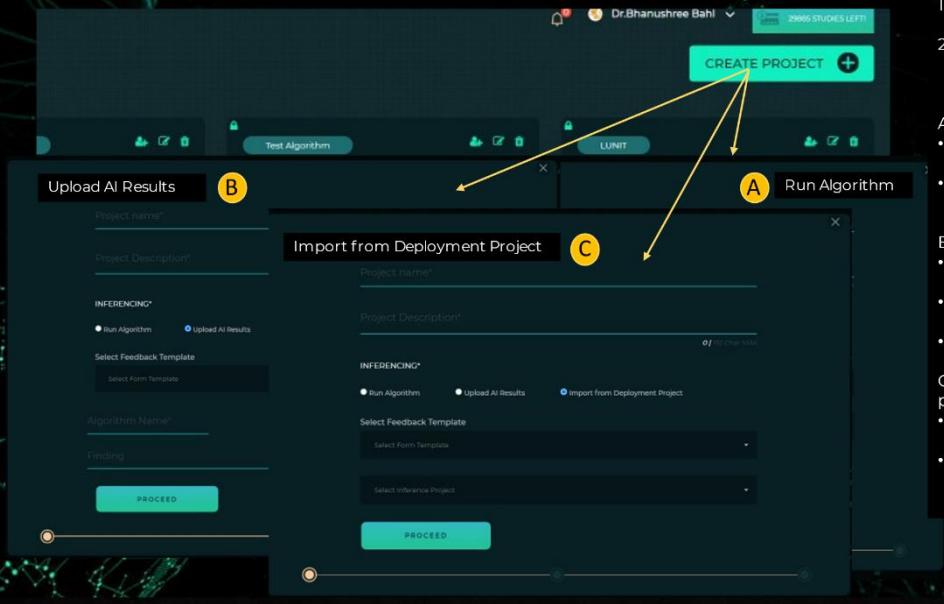
Pre-Deployment Test: Classification- Create Project



1. Project Details- Add project details
2. Inferencing- **A. Run Algorithm, B. Upload AI results, C. Import from deployment project**

A. Run Algorithm:
- Feedback Template- User can select a feedback template
- Algorithm- Select an algorithm in order to run the inferecncing on a dataset

B. Upload AI Results:
- Feedback Template- User can select a feedbacktemplate
- Algorithm Name: Fill in the name of the algorithm
- Findings: Fill in the findings of the algorithm

C. Import from deployment project:
- Feedback Template- User can select a feedback template
- Inference project: Select an inference project you want to link it to.

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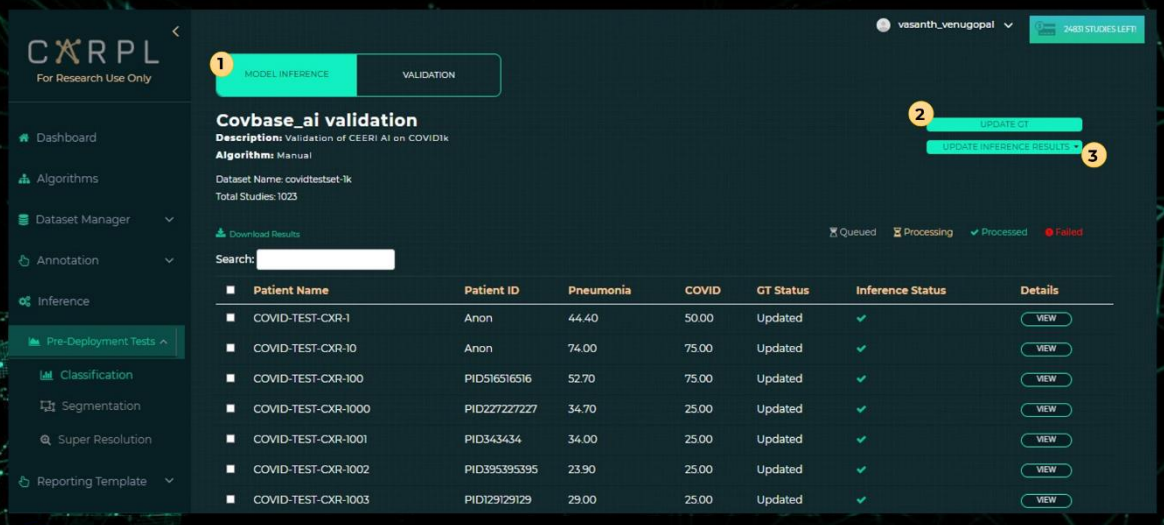
Pre-Deployment Test : Classification: Model Inference



1. "Model Inference" will give summary output of validation results
2. Use "Update GT " to upload GT
3. Use "View" to visualize the case in CARPL DICOM Viewer

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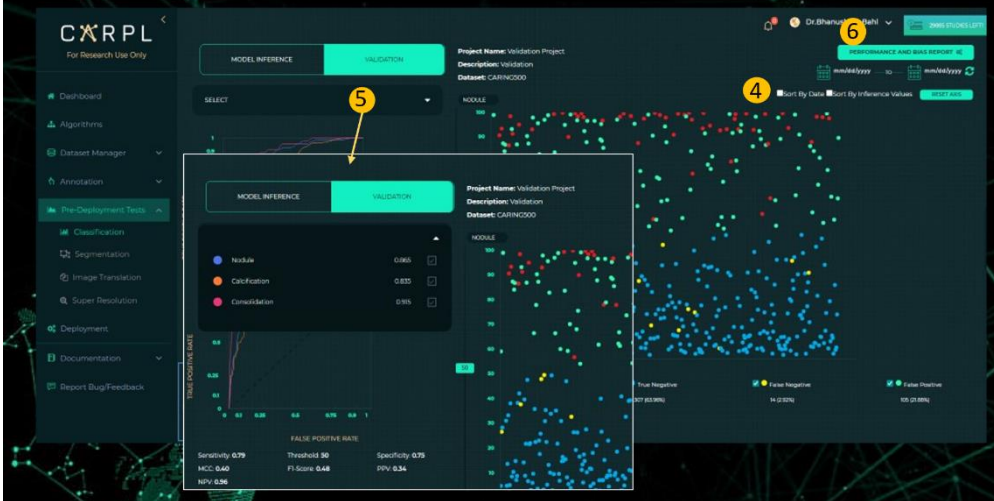
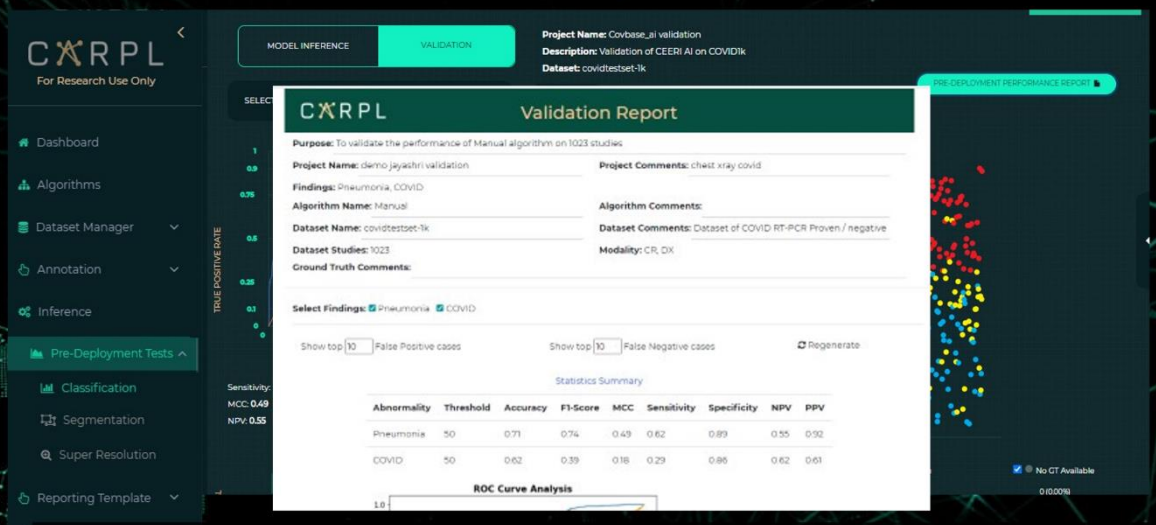
Pre-Deployment Tests- Classification: Validation



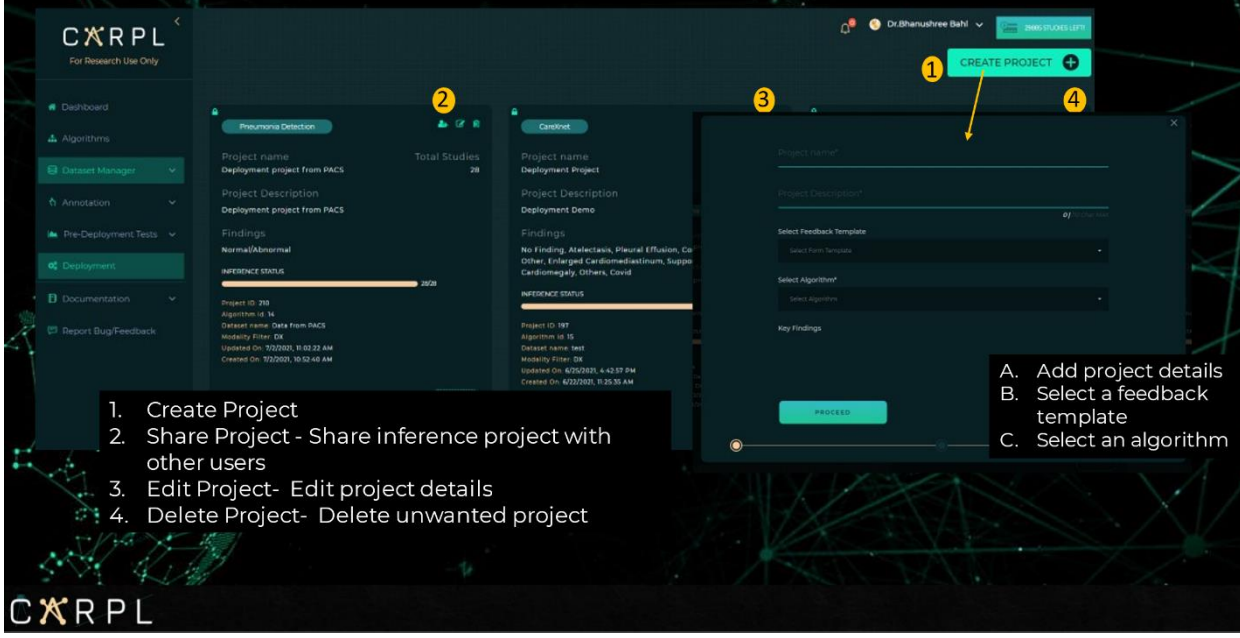
1. Threshold- With the help of the bar, increase or decrease the threshold for a abnormality
2. Confusion Matrix- View the confusion matrix for the validation
3. Performance Matrix- View the performance of the validation
4. Sort by Date/Inference Values- Sort the cases according to date or inference values
5. Select Abnormality- Select a abnormality to view the validation
6. Performance and Bias Report- Generate a performance or bias report in a PDF format for the validation project

Validation: Classification: Validation Report



- Clicking on the Pre-deployment performance report will give you Validation Report for Classification algorithm
- Regenerate- You can change the number of False Negatives/Positives to be shown in the report and regenerate it

Deployment

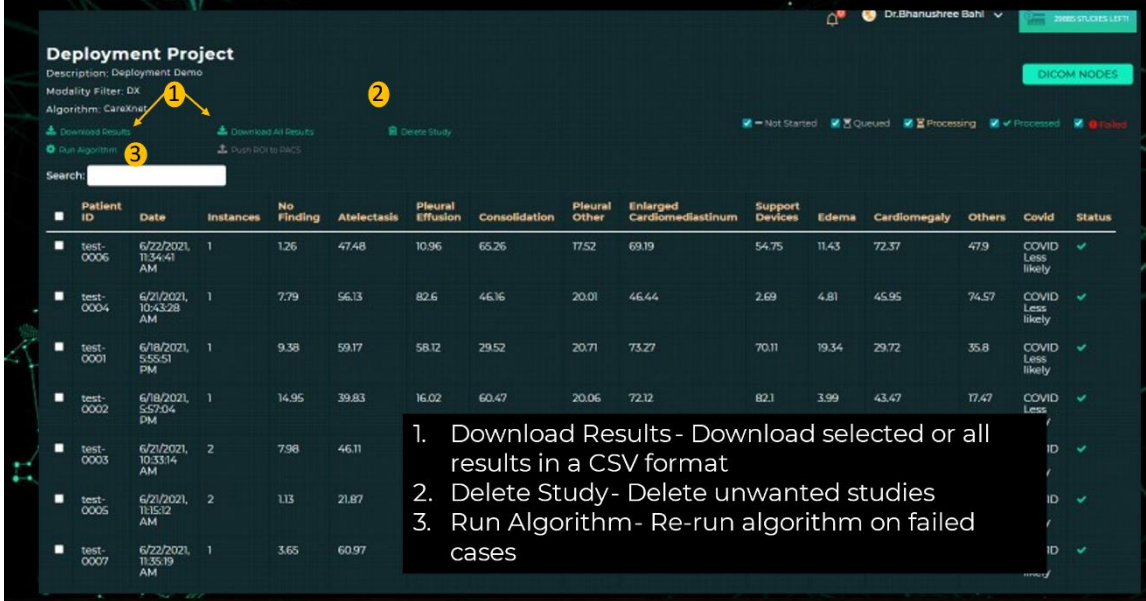


1. Create Project
2. Share Project - Share inference project with other users
3. Edit Project- Edit project details
4. Delete Project- Delete unwanted project

A. Add project details
B. Select a feedback template
C. Select an algorithm

CXRPL

Deployment

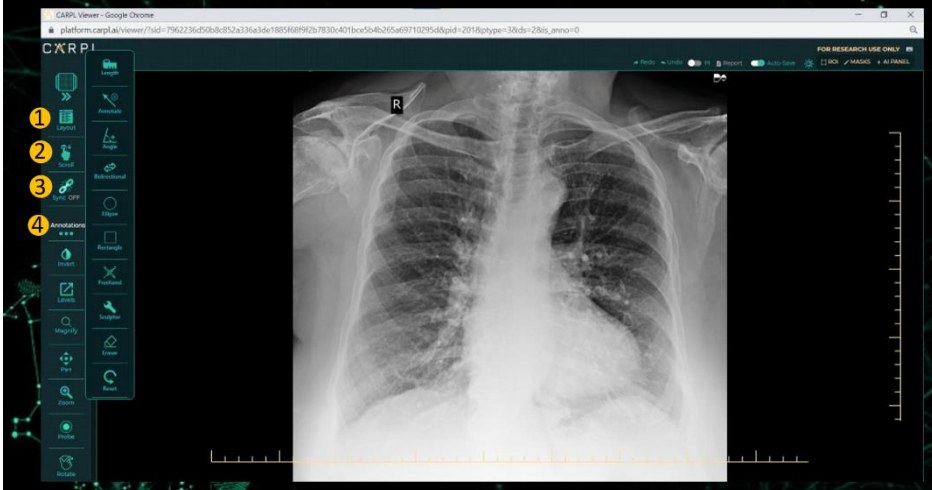


1. Download Results - Download selected or all results in a CSV format
2. Delete Study - Delete unwanted studies
3. Run Algorithm - Re-run algorithm on failed cases

CXRPL

CARPL Viewer:

CARPL has in-built DICOM viewer with all the functionalities



1. Layout- Choose how many panes with study images to preview. You can choose from one to nine panes for different images
2. Scroll- It allows you to scroll through images one at a time or easily scroll through images of a series
3. Sync-off- It allows the you to scroll through images one at a time or easily scroll through images of a series
4. Annotations- You can annotate an image, click on 'Annotation', a collapsible bar opens, which contains many tool bars which can be used to annotate a case

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CARPL Viewer:

1. Invert- This button is used to invert the study image, clicking on it once inverts the image, if clicked second time it resets the image back to its original state
2. Levels- This tool is used to compare the window width and window centre features of a study
3. Magnify- This tool is used to magnify (enlarge) a certain area on the image
4. Pan- Panning of the image is done to view the area of image which is not visible in viewing panel
5. Zoom- This tool is used to zoom in or out the image

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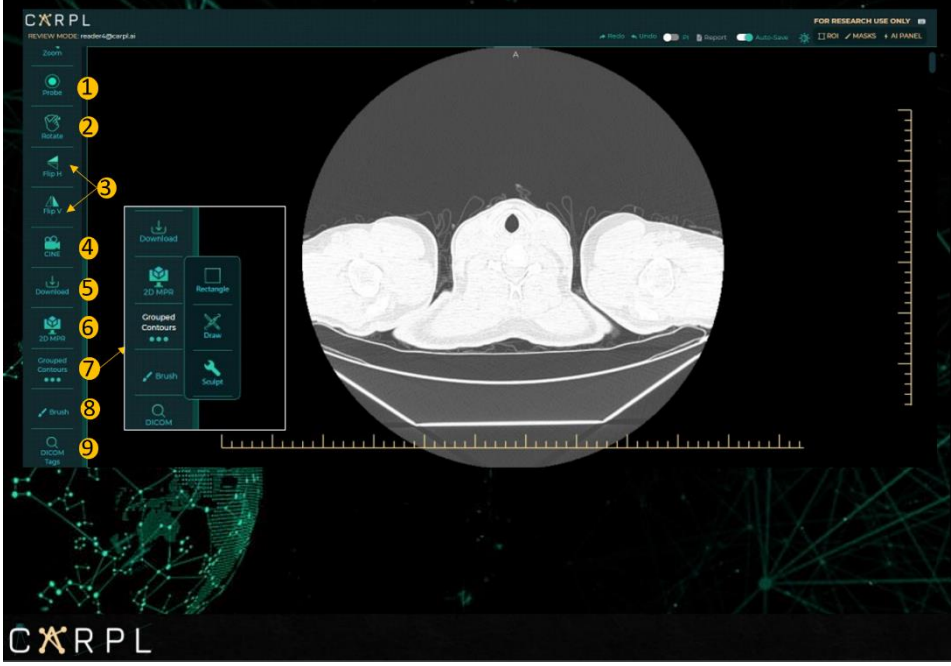
CARPL Viewer:



1. Probe- This tool is used to look at the pixel values of the area under your cursor on the image
2. Rotate- This tool is used to rotate the image 90 degreesclockwise
3. Flip H and V- Either of the option is used to flip the image 180 degrees horizontally or vertically
4. Cine- This tool is used to put all the images in a series into onemovie
5. Download- User can download the image to its system by using this option. When user selects 'Download' a pop up appears where user has to select the format of the image, file name, image width and height and can also disable 'Show Annotation'option
6. 2D MPR- This tool is used to view the image in 3D
7. Grouped Contours- This tool is used for Multi slice ROIs with interpolation
8. Brush- Brush tool for masking the lesions
9. DICOM Tags- This option provides all the DICOM metadata that is related to that study

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