From Logistics to Seamless Analysis:
Enhancing Medical Imaging Efficiency with DiSoft

Overview

Lambda Therapeutic Research is a leading CRO with extensive experience in delivering high-quality medical imaging analysis across various therapeutic areas.

Lambda, in collaboration with **Sarjen Systems Pvt. Ltd**., has developed **DiSoft (Diagnostic Imaging Software),** a customized **web-based global imaging** application. DiSoft enables the secure uploading, analysis, and storage of images for the evaluation of clinical trial endpoints.

DiSoft goes beyond offering premium image analysis capabilities by providing the flexibility to customize and meet specific client requirements. It ensures **secure access** from any location **worldwide** through web-based portals, guaranteeing convenient and reliable access to stored images for evaluation and analysis purposes.

DiSoft Features

- Compliant with 21 CFR Part 11, Protected health information (PHI), GDPR & GxP.

- GAMP 5 validated software.

- Secure operation, hosting, database storage & backup.

- Supports different types of image uploads (CT, PET-CT, MRI, X-Ray, DXA, FA, CFP, OCT) with de-identification of confidential patient information.

- Single/Double Quality Checks.

- Single/Double Grader review assessment & Adjudicator review where applicable.

- Efficacy data export.

- Audit trail facility capturing user credentials, changed values, date & time of changes, ensuring data integrity.

- Automated alert emails to notify respective stakeholders about various activities.

- Certification of sites within the database based on study-specific requirements.

- Customized Edit-checks.

Extensive
Capabilities

Oncology with capability of evaluation methods RECIST 1.1 and Cheson 2014.

Musculoskeletal for evaluation of Dual X-ray Absorptiometry (DXA) (Densitometry & Ancillary data) and X-ray (Genant Semiquantitative (SQ) scoring method).

Ophthalmology for independent assessment of Age-related Macular Degeneration (ARMD) imaging with different image types Color Fundus Photograph (CFP), Fluorescein Angiography (FA) and Optical Coherence Tomography (OCT).

Future expansion planning for **iRECIST evaluation** method, **Gastrointestinal (GI) imaging.**

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DiSoft-C

- Independent assessment of RECIST 1.1 (Solid tumours) & Cheson (Lymphomas)

- Handles CT, PET-CT and MRI

9 Studies Conducted

DiSoft-D

- Independent assessment of Osteoporosis imaging

- Handles DXA & X-ray

- Works with GE enCORE software

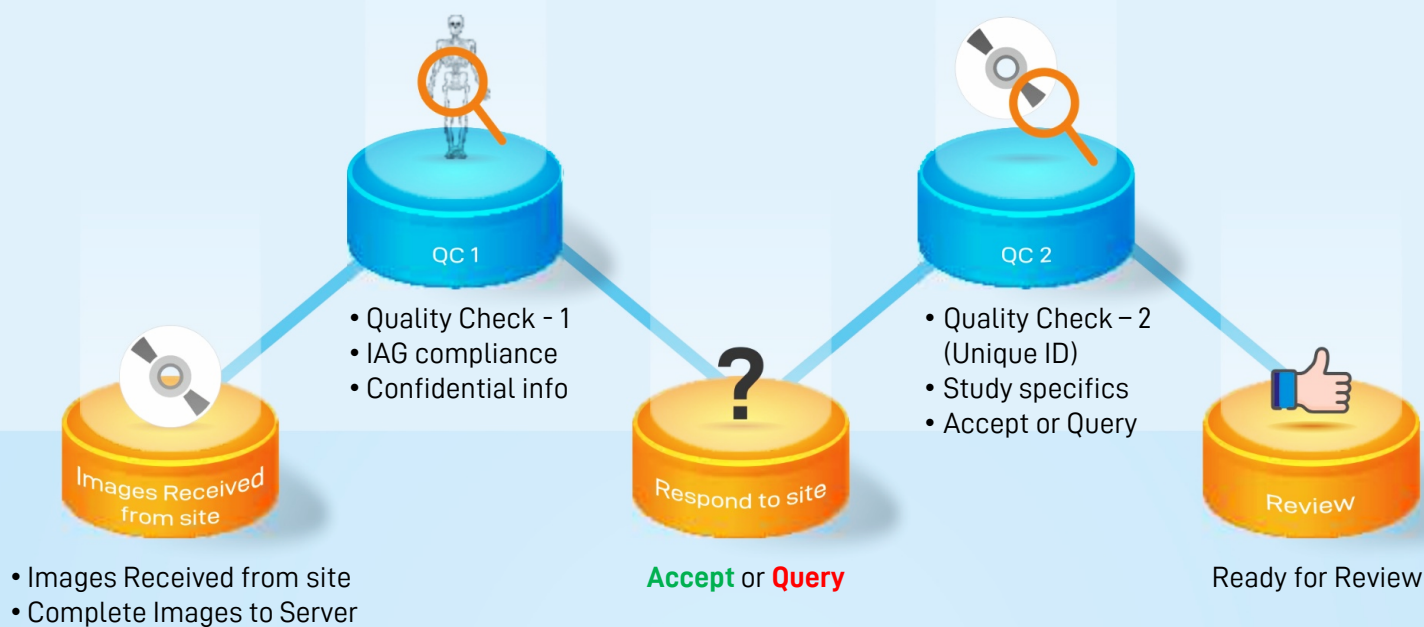**2** Studies Conducted

DiSoft-E

- Independent assessment of Age-related macular degeneration (ARMD) imaging

- Handles OCT (Cirrus, Spectralis, Optovue, Topcon), FA, CFP

- Works with Orion (a manufacturer-agnostic OCT software)

1 Study Conducted

Operational Workflow
- Quality Assessment

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Image Quality Checks @ Lambda

QC 1

QC 2

- Quality Check - 1
- IAG compliance
- Confidential info

- Quality Check – 2 (Unique ID)
- Study specifics
- Accept or Query

Images Received from site

?
Respond to site

Review

- Images Received from site
- Complete Images to Server

Accept or **Query**

Ready for Review

48 Hours

Site sends images to Lambda by using DiSoft web version.
Lambda responds to the site.