

ENHANCING THE EFFICIENCY OF TOXICOLOGIC PATHOLOGY

Augmentiqs is a
platform for *Real-Time
Telepathology &
Online Peer Review.*





**It's being used to reduce costs
of investigative & regulated
preclinical studies by enabling
faster & more informed clinical
decisions.**

Online Peer Review

Pathology evaluation is the limiting step in toxicological studies.

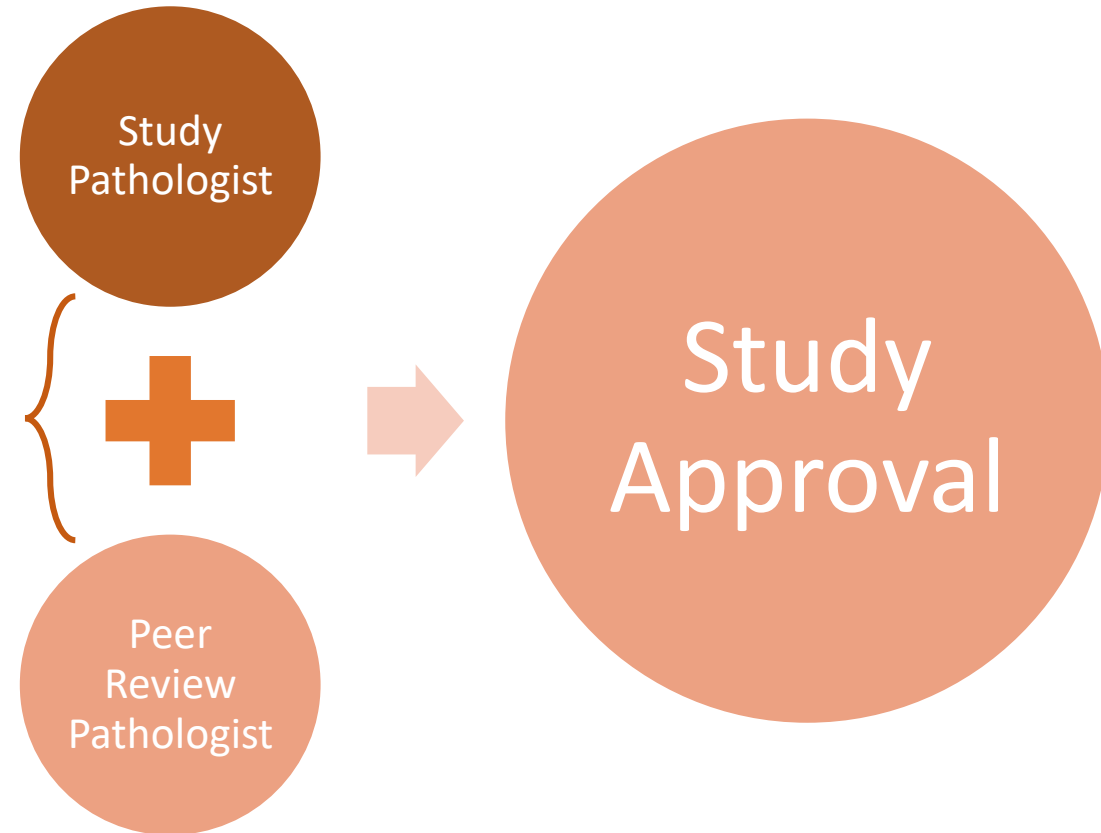
Sponsor & CRO pathologists frequently consult, or conduct a peer-review.

In the event of disagreement, the pathologists must meet **to see the slide together and** discuss the findings.

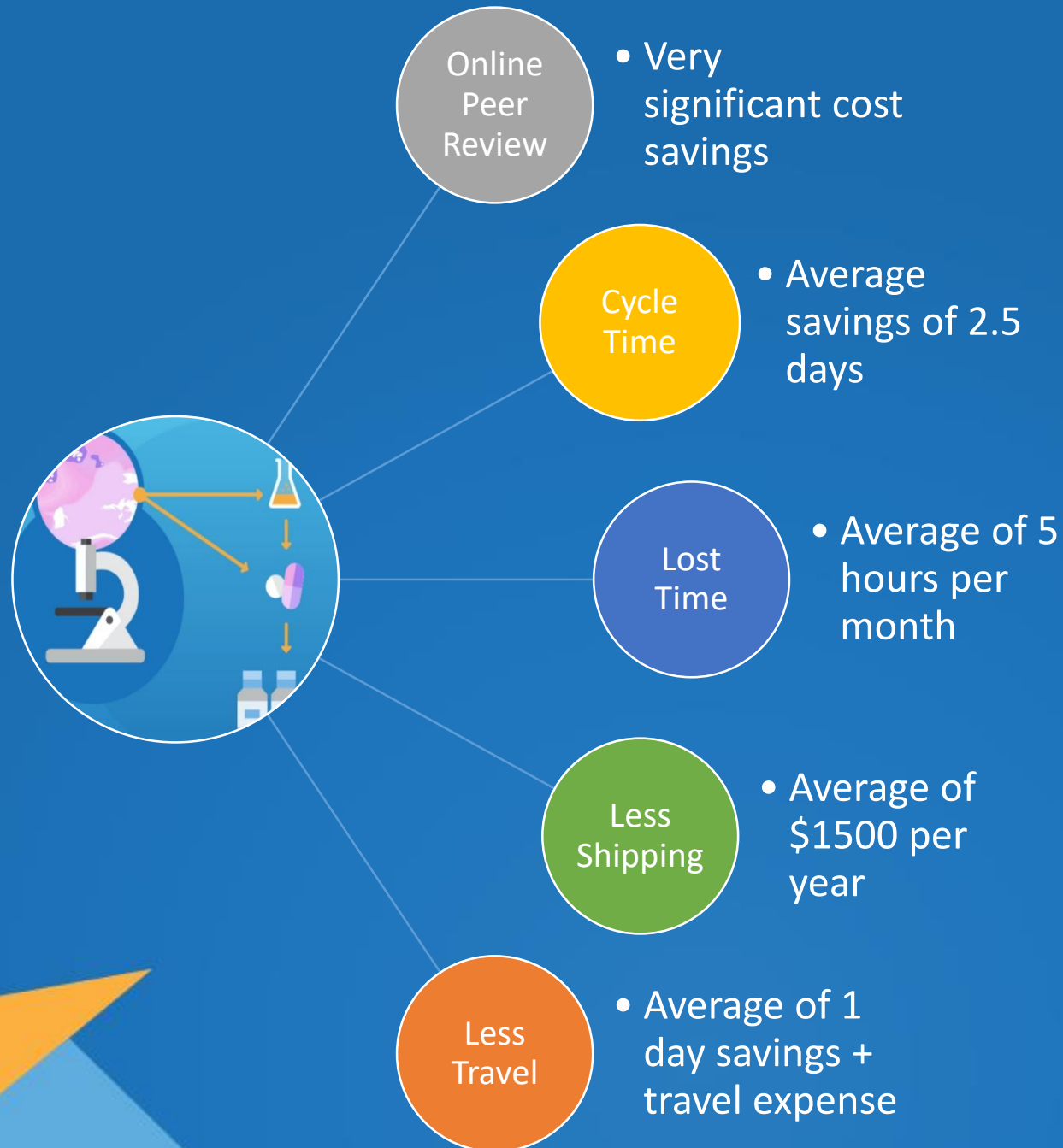
The ultimate and most frequently used method is to fly or ship the slides - both are costly & time consuming.

Lost Resources:

- Time to market
- Length of study
- Pathologist time
- Travel expense
- Logistic expense



The Path to a Fast ROI

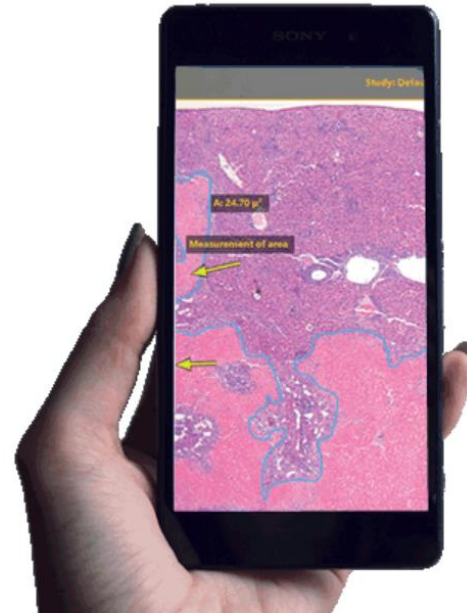
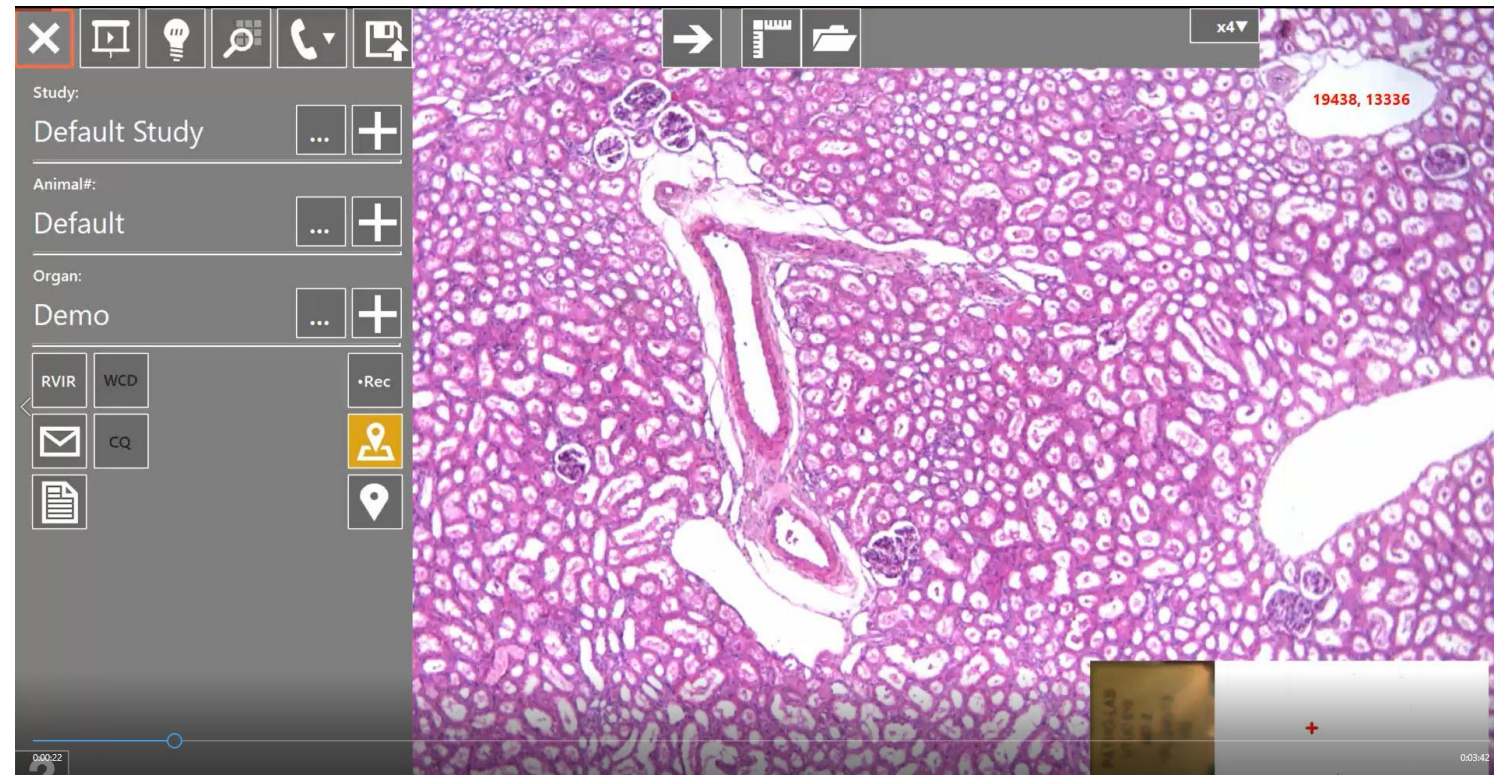


**A single use of Augmentiqs for an online peer review will result in a complete ROI, and large cost savings.*

*** A recent cost-analysis study of Augmentiqs conducted by a CRO has found ROI to be reached within just a couple months when used solely for routine work.*

Reducing costs by enhancing the workflow.

- *Telepathology*
- *Database*
- *Annotations & morphometrics*
- *Publication-grade image capture*
- *Advanced analytics*
- *Automatic reporting*
- *WSI data sharing*
- *More..*



**Augmentiqs
enhances workflow
& keeps costs low
by integrating within
the pathologist's
existing microscope.**



System Advantages:



Quick ROI

- Speeds up study timeline
- Reduces need for travel & logistics
- Modular system fits existing microscope



Real-Time Telepathology

- Unlimited number of remote viewers
- Live view of tissue
- Multi-directional annotations for all users

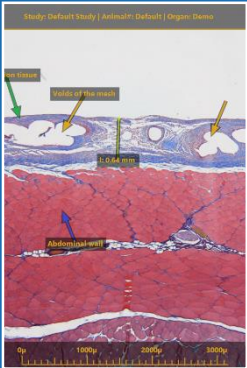
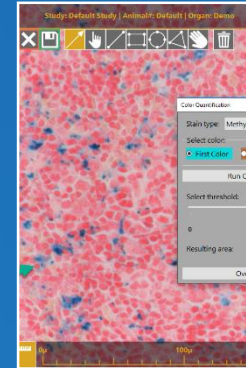


Image Quality

- Very high resolution (TIFF/PNG)
- Lossless compression
- Full field of view



Modern Capabilities

- Send images to cell phone or email
- ImageJ & other analytical toolsets
- Open API for running legacy SW



Integrated System

- Complete HW & SW solution
- Data integrates with WSI
- Highly secured IT compliance

Clinical Validity:

Augmentiqs has been:

- i) utilized in online peer review,
- ii) published in peer-reviewed journals,
- iii) presented at STP conferences,
- iv) used in FDA submissions.

Introduction

Pathology peer review of toxicologic pathology findings in safety assessment studies of drugs, food additives and agrochemicals is commonly done prior to submission of test results to regulatory authorities. Following completion of pathology evaluation of preclinical toxicity studies, histopathology slides are often shipped to the peer review pathologist (PRP), or the PRP would travel to the study pathologist (SP) facility to review the histopathology slides with the SP using a double headed microscope.

The purpose of our study was to determine if new telepathology technologies can effectively be used for the peer review aspect of the preclinical study, and thus reduce need for travel and logistic expense.

Materials

A novel telepathology system (Augmentiqs™) (Siegel et al. 2017) becomes an integrated component of the pathologist's existing microscope by being placed in the optical path above the nose piece and below the eyepieces (Figure 1). The pathologist continues to view the optical plane of the tissue through the microscope eyepiece, while an embedded image sensor within the telepathology system captures a live feed of the tissue on the microscope stage. Without the use of whole slide scanning, the telepathology system enables remote parties to view and discuss a live image that is of high digital-pathology grade, and similar to the dimensions of the tissue as seen within the microscope eyepiece.

Multiple remote parties are able to view the live telepathology session from their own computer after downloading a client viewing software. All participants may save digital-pathology grade images of the tissue directly to their computer. The dynamic nature of the telepathology technology allows remote parties to perform and view all annotations or morphometric calculations during the slide evaluation phase of the telepathology session. The audio part of the live discussion may be conducted using a regular telephone or using communication programs such as Skype.

Figure 1



Figure 1. Optical module installed on microscope.

Methods

Following completion of the pathology evaluation of preclinical toxicity studies at contract laboratories located in the U.S. and Europe, histopathology slides are shipped to the PRP located in Israel. The PRP then utilizes the novel telepathology system from his existing microscope in order to discuss histopathology diagnoses and reach a consensus, and thereby avoiding the need to travel to the SP situated at the contract laboratories.

Experimental Design

Three recent examples of pathology peer review were carried out using this novel system for telepathology.

The slides chosen for the peer review were those which had lesions which the PRP questioned or did not agree with the classification of the lesions provided by the SP.

The two pathologists would work to obtain a consensus while simultaneously viewing and discussing the selected slides as they were under the microscope. The PRP with the novel telepathology system would work normally, including the use of moving the mechanical stage, changing focal plane objectives as needed for increased

Results

Within a timeframe ranging from 1-2 hours, multiple selected slides were reviewed. Participants could see the actual slides projected from the microscope of the PRP, discuss the lesions, annotate, and save high resolution images on their computers.

Upon completion of the slide review, the PRP prepared a "Live Telepathology Review Report" which documented the procedure of the review of slides, use of the live telepathology technology, and representative photos of all microscopic fields of the slides which were shared. This unofficial report served as study notes and was sent from the PRP to the SP.

Eventually, the SP and PRP signed a Formal Peer Review Statement indicating that the revised report reflects the consensus achieved by the pathologists during the telepathology session. This document was eventually included in the formal study report that was submitted to FDA.

Examples of photos, which include annotations and morphometric data taken by the Augmentiqs live-telepathology system from unrelated studies, are in Figure 2 A-D.

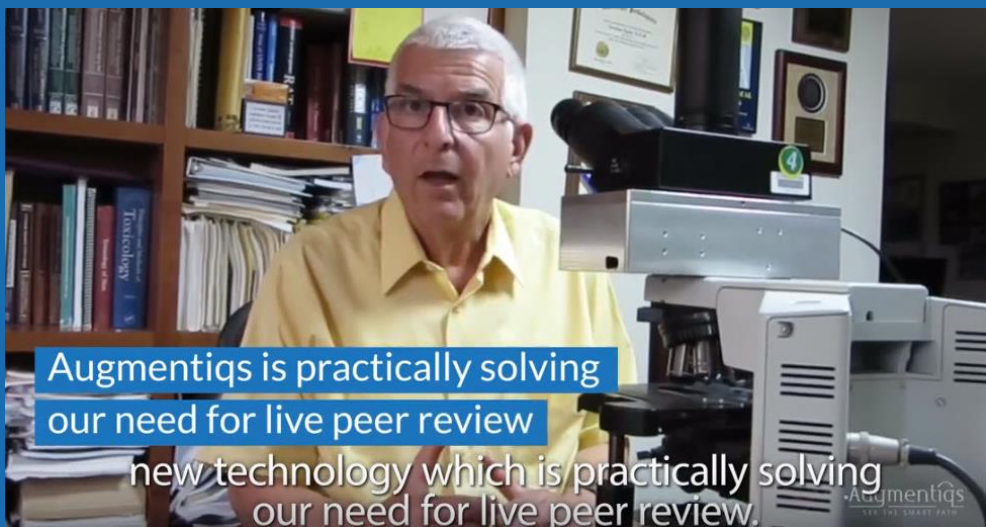
STATUS

Being Used by CROs & Pharmaceuticals

Charles River Laboratories | WUXI | Integrated Laboratory Systems | Research Toxicology Centre | Teva Pharmaceuticals | Mitsubishi Pharma | More..



TESTIMONIALS



Augmentiqs is practically solving
our need for live peer review

new technology which is practically solving
our need for live peer review.

<https://www.youtube.com/watch?v=Qq8yv9EU1W8>

Dr. Stephen Hewitt, NIH/NCI



"I will be ordering several of these for my lab."

Dr. Bob Maronpot, Former Director NIEHS



*"Great new technology. It will improve workflow, and
give benefits not available today."*

Dr. Shimo Hayashi, San-Ei Gen



"This is an excellent technology."

Dr. Dan Rudmann, Charles River



"Augmentiqs is Quality, Value & Speed."

Dr. Moti Rozenstein, Teva Pharmaceuticals



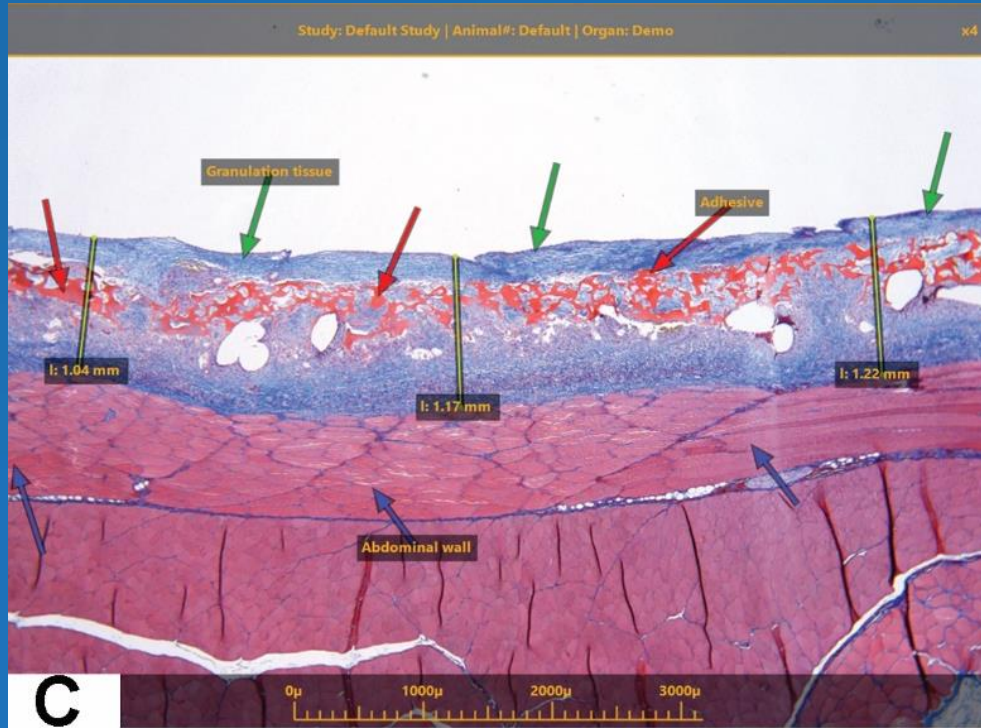
"Better than the gold-standard."

Dr. Maurice Cary, Pathology Experts

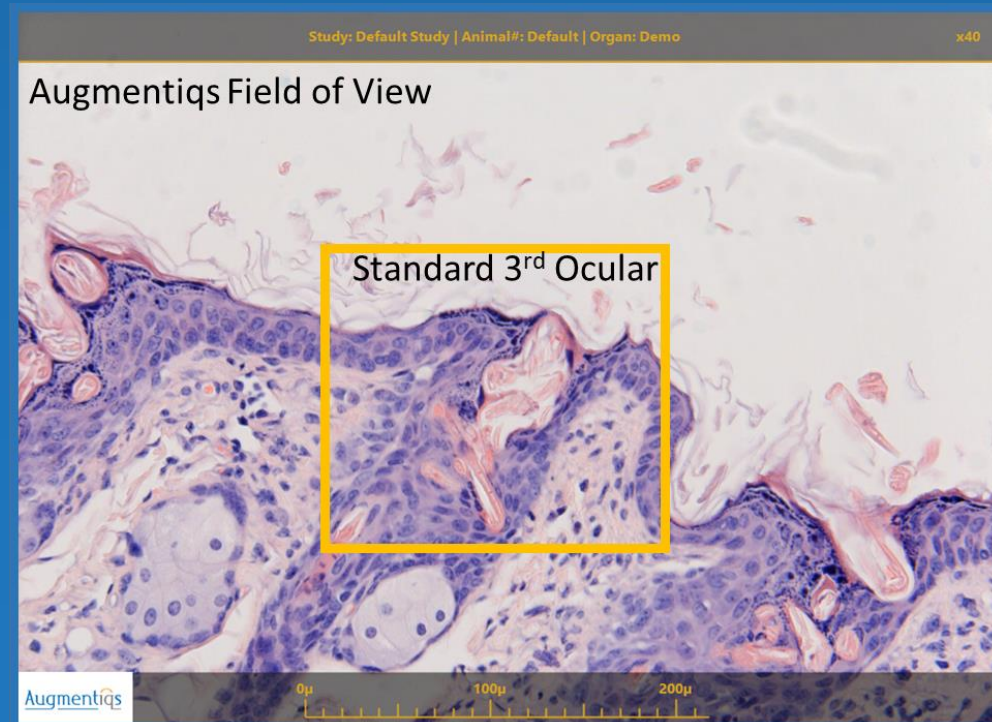


*"You guys are amazing... And honestly, that's an
understatement"*

Augmentiqs is Your Virtual Multi-Headed Microscope for Toxicology Studies



Real-time & multi-directional telepathology with annotations & HD image download



Providing remote viewers with a full view of the tissue as seen within the eyepiece.



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