

# Case study with Boehringer Ingelheim Pharmaceuticals, Inc.

## Developing AI-based quantitation of DSS colitis



### OBJECTIVES AND BACKGROUND

- Can we validate and deploy AI-based image analysis as a tool for pathologists to enhance the speed, accuracy and comprehensiveness of DSS colitis analysis?
- Decrease usual 4 week turnaround and do more in same timeframe
  - H&E slides validated by AI within two days
    - Molecular testing can be run without risk
    - Capturing many histopathological variables to direct pathologist toward results not normally sought after
  - Increase speed, quantitation, and scope
  - Pathology scoring is a bottleneck in current DSS analysis workflow

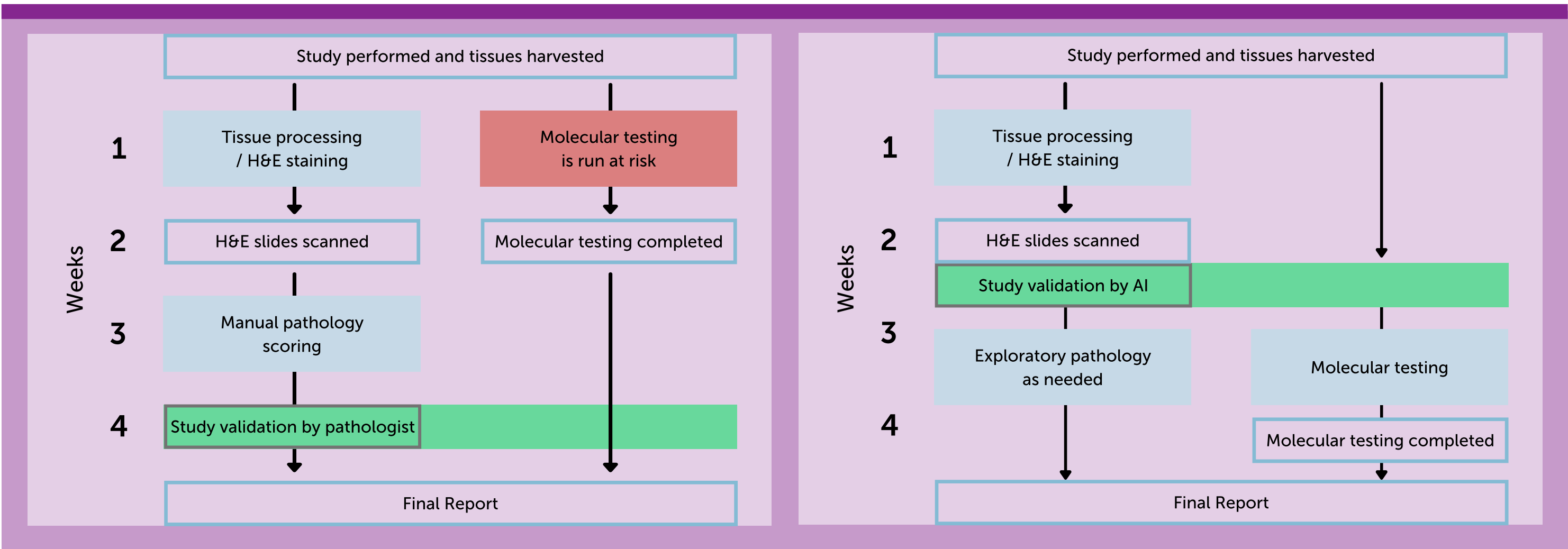
### STUDY DESIGN

- Model of damaged intestinal epithelial barrier in immune competent mice
- 3% Dextran sodium sulphate (DSS) to drinking water for five days
  - DSS is toxic to epithelial cells, damaging intestinal tract
- 4 DSS studies were run internally, all scored using 3 categorical parameters: epithelial changes, inflammation, ulceration
- Digital whole slide images of H&E stains scanned
- Uploaded to cloud-based Aiforia software
- AI model developed with Aiforia Create to quantify DSS colitis histopathology

### WORKFLOW

- 1 Tissue processing / H&E staining
- 2 H&E slides scanned
- 3 Study validation by AI: Trained AI to recognize mucosal features used histology scoring
  - Study pathologist worked with Aiforia to define 9 features
  - Initial AI algorithm detected ulceration false positives and negatives → retraining
- 4 Further validation of AI score vs histology score using Kozlowski method
- 5 AI algorithm successfully validates each of the 4 DSS studies used
- 6 Exploratory pathology
  - Added additional features as exploratory endpoints to test compound differentiation
  - Ended up with 70 parameters defined using raw area and normalised area scores
  - Comparing area scores vs normalised scores

### OLD WORKFLOW VS POSSIBILITIES WITH AI IMAGE ANALYSIS



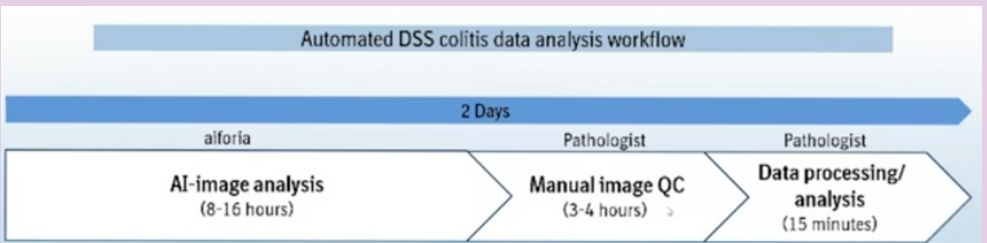
### BENEFITS OF AI-ASSISTED ANALYSIS

- Speed: scoring 100 animals will take 2 weeks at top speed
  - AI cuts it down to 2 hours
- Quantitation: subjective categorical histopathology scoring
  - AI image analysis can get fully quantitative continuous variable result
  - Decrease variability in scoring
  - Increase statistical power of analysis
  - Use fewer animals to meet same endpoints
- Scope: time constraints mean limited number of parameters measured
  - Use AI to collect more histopathological features
  - Analyze those features in reaction to many different compounds

### CONCLUSIONS

- Generated AI-algorithm to quantify DSS colitis histopathology using Aiforia
- AI-ulcer score is highly correlated with manual ulcer histology score
- AI-ulcer score did not provide a power advantage over histology score
- AI scoring provides many novel exploratory scores beyond manual histology

Improved workflow:



### RESULTS

- Mean scores and score variability is similar between AI and Histology
- Variability driven by different DSS/treatment responses between animals
- No meaningful difference in sample size between ulcer scoring methods
- Significant difference in ulcer area associated with sulfasalazine treatment
- Sulfasalazine impacts ulcer area and total lamina propria more than submucosa area

### FUTURE DIRECTIONS

- Next round of training will increase accuracy and robustness of ulceration scoring
- Validate AI workflow with head to head comparison to standard pathology using prospective DSS study
- Expand into other disease models (T-cell transfer; CD40-agonist)
- Add new feature detection to digitize other manual pathology scores

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demo?

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