Standards for Imaging Endpoints in Clinical Trials: Management of Imaging Data

Display Issues

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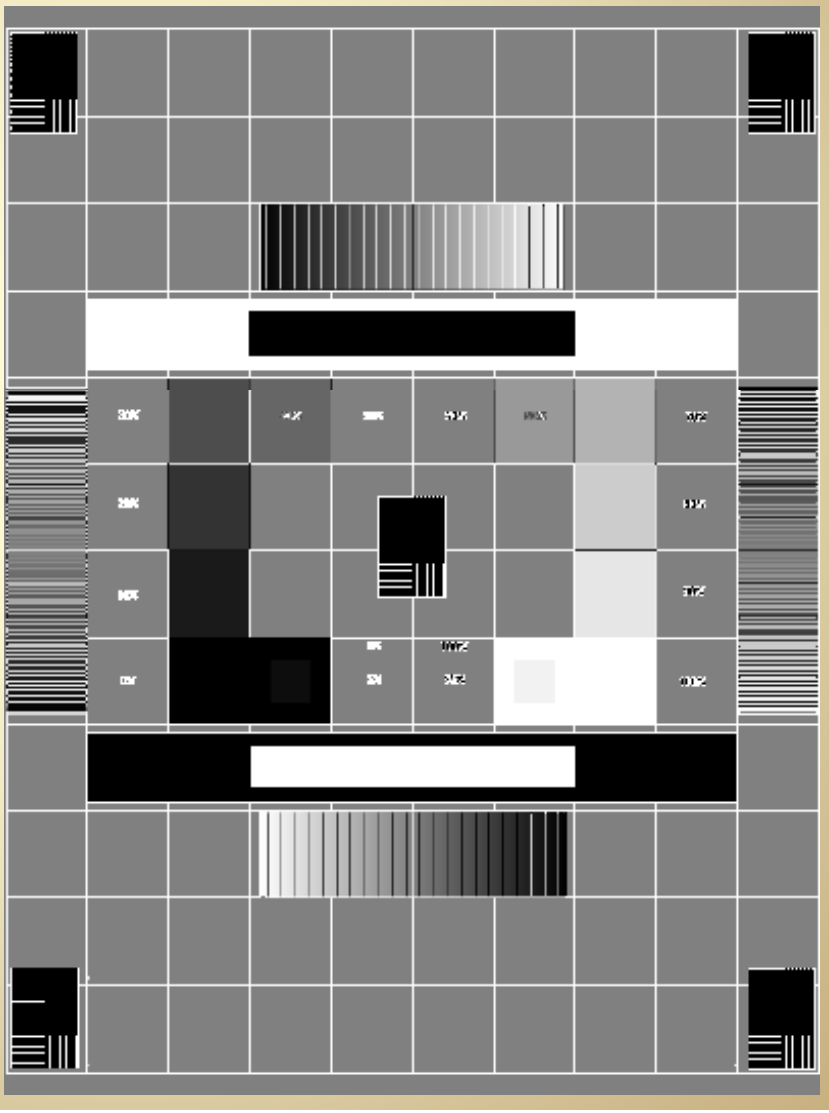
Monitors

Important to Standardize Viewing Conditions and Monitors

- Monitor contrast and spatial resolution
  - Requirements may vary according to type of study being interpreted
  - Can be evaluated in a number of ways including using high resolution SMPTE pattern

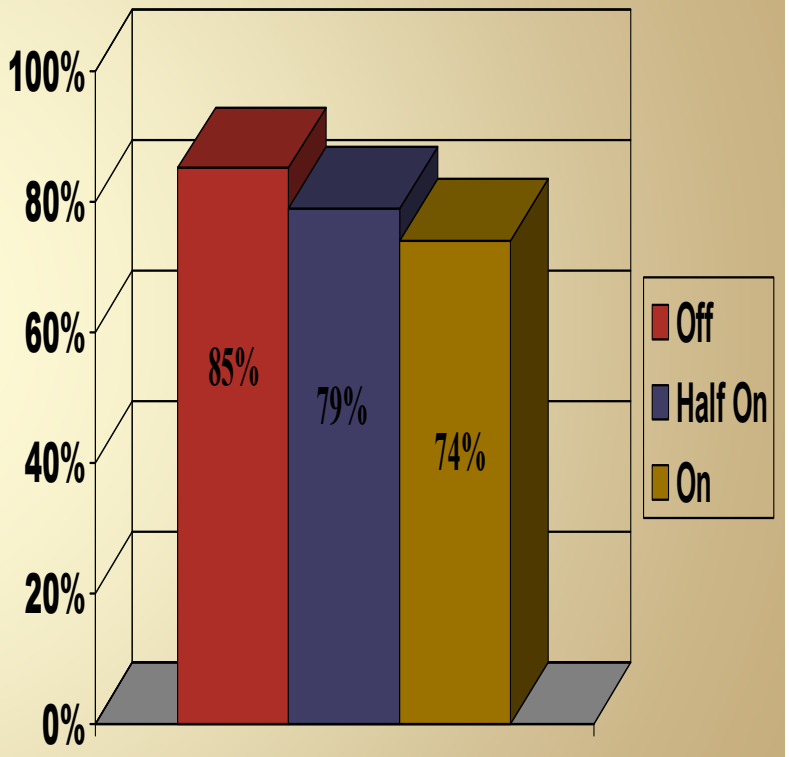


Important to Standardize Viewing Conditions and Monitors

- Monitor size
  - Should be standardized but bigger seems to be better in general
- Monitor calibration
  - Is increasingly becoming automated for “medical grade” monitors

11% Decrease in Image Interpretation Accuracy with Monitor to Ambient Mismatch

- Monitor brightness
  - Has been shown to be critical issue for image interpretation especially for perception of differences in gray scale
  - Mismatch between monitor brightness and ambient room lighting has been shown to result in a major decrease in image interpretation accuracy



- Video card characteristics
  - Often overlooked, can have mismatch of video card resolution and monitor resolution
- How long will be monitor take to warm up?
- Monitor grayscale display
  - New monitors claim up to 11 bits but virtually all current software is limited to 8 bit display
- Should all images in a clinical trial/study be read on the same monitors?

How Can We Minimize Differences Among Monitors?

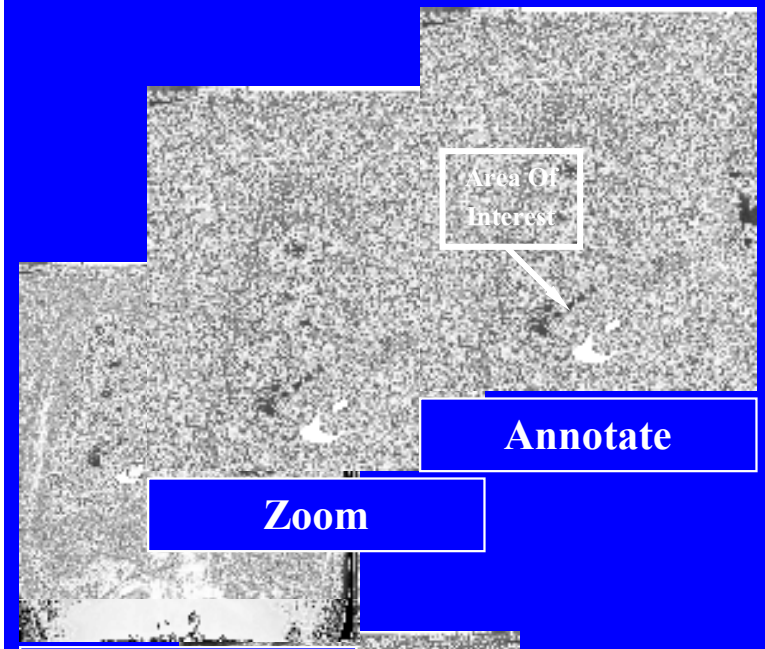
- DICOM attempts to address this

DICOM Image Consistency Efforts GSDF, P-LUT, and GSPS

- Grayscale Standard Display Function (GSDF)
  - Minimize differences in perceptual differences among monitors and printout on film
- Specifies exactly what luminance or density level should be produced for a certain input value, based on the Barton curve, which maps the values into a range that is perceptually linear
- This means that input values are mapped into a space that is perceived as linear by a human observer

- Presentation LUT (P-LUT)
- Grayscale Softcopy Presentation State (GSPS)
  - Stores parameters used to view images
- And in actual practice…
  - Are widely & effectively implemented
  - Via IHE Consistent Presentation of Images solution:

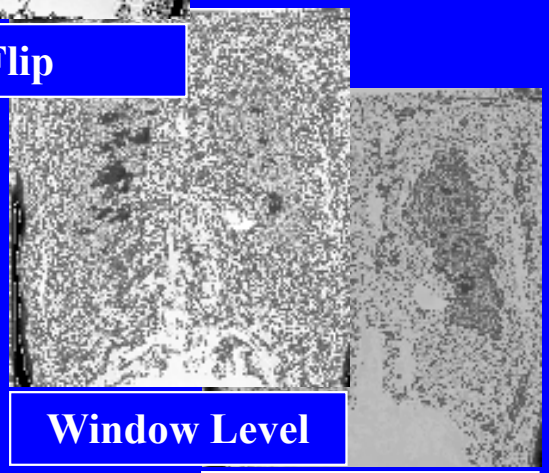
What the Radiologist Displays:



Annotate

Zoom

Flip



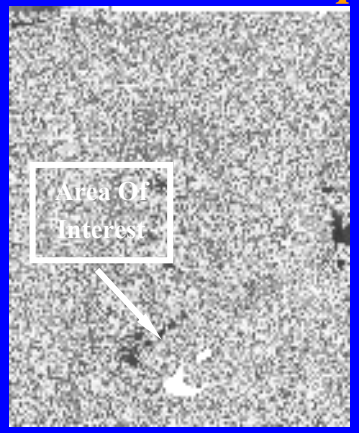
Window Level

Original Image

What the Reviewing Physician Sees:

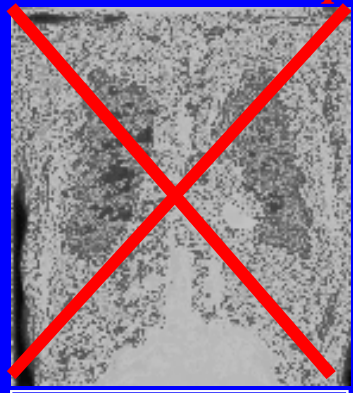
Consistent Presentation of Images On a Calibrated Display

The Radiologist's Transformations Are Saved



Inconsistent Presentation On an Uncalibrated Display

The Radiologist's Transformations Are Lost



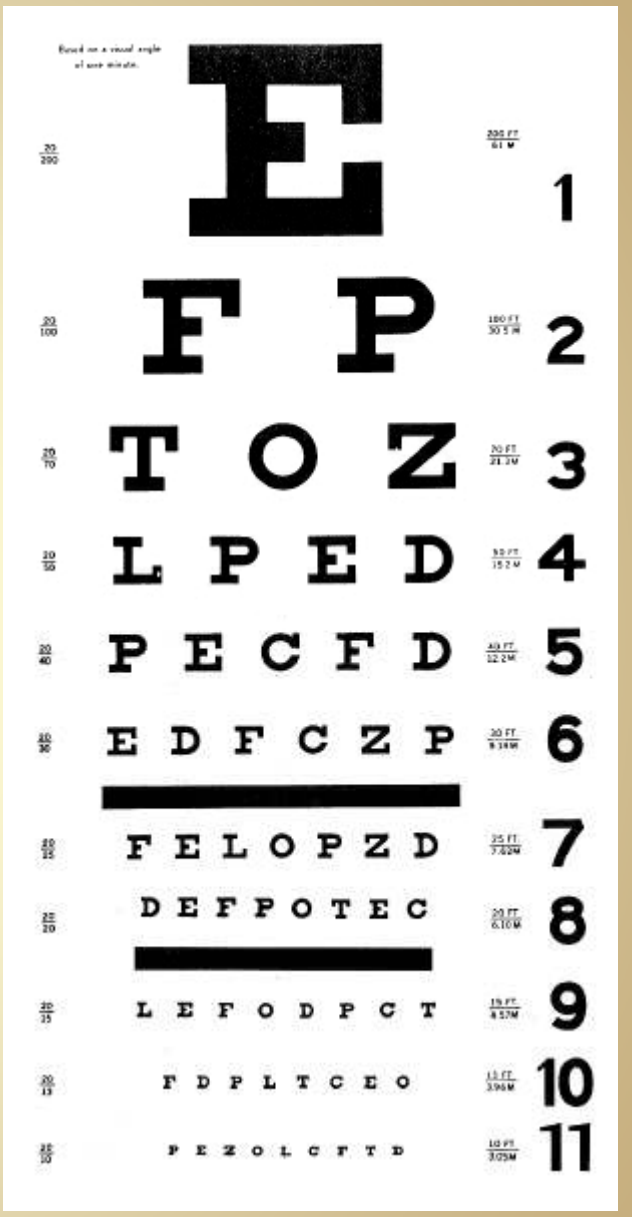
Original Image

Software

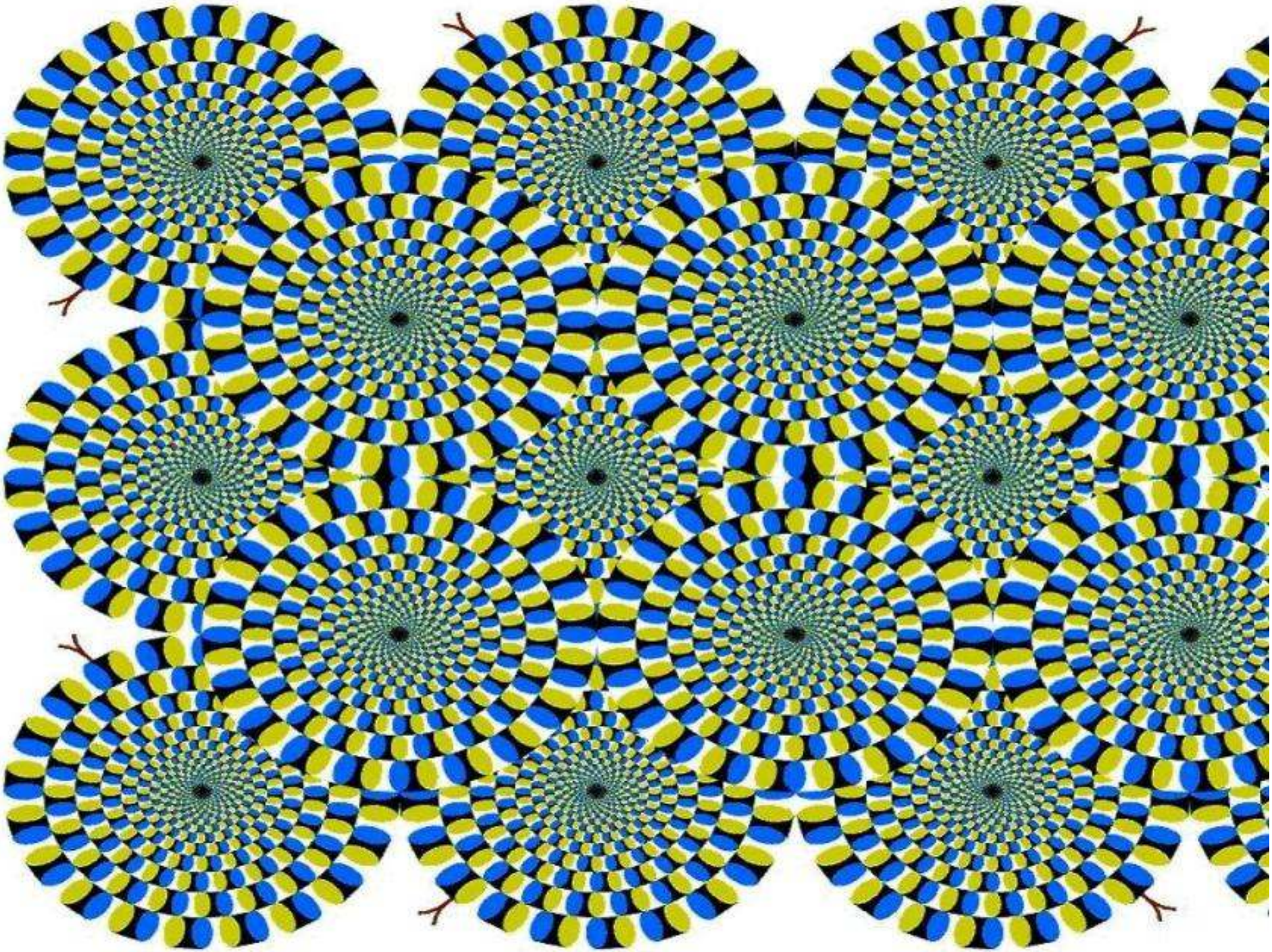
- Need to standardize presentation of the images

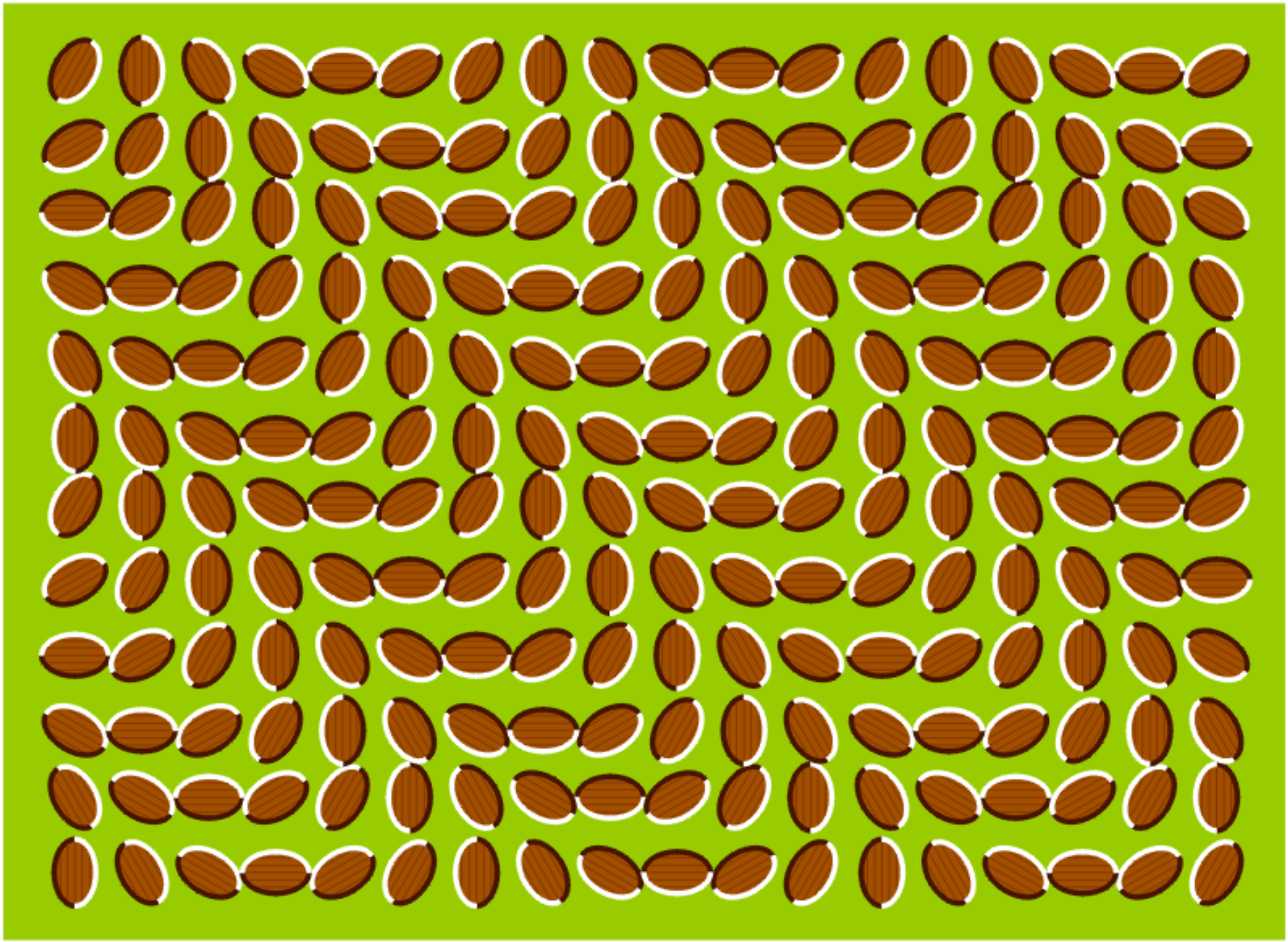
Ambient Lighting

- Standardize ambient lighting conditions for review and issues such as distance from display and even reader visual acuity



Additional Processing in the Visual System and Visual Cortex

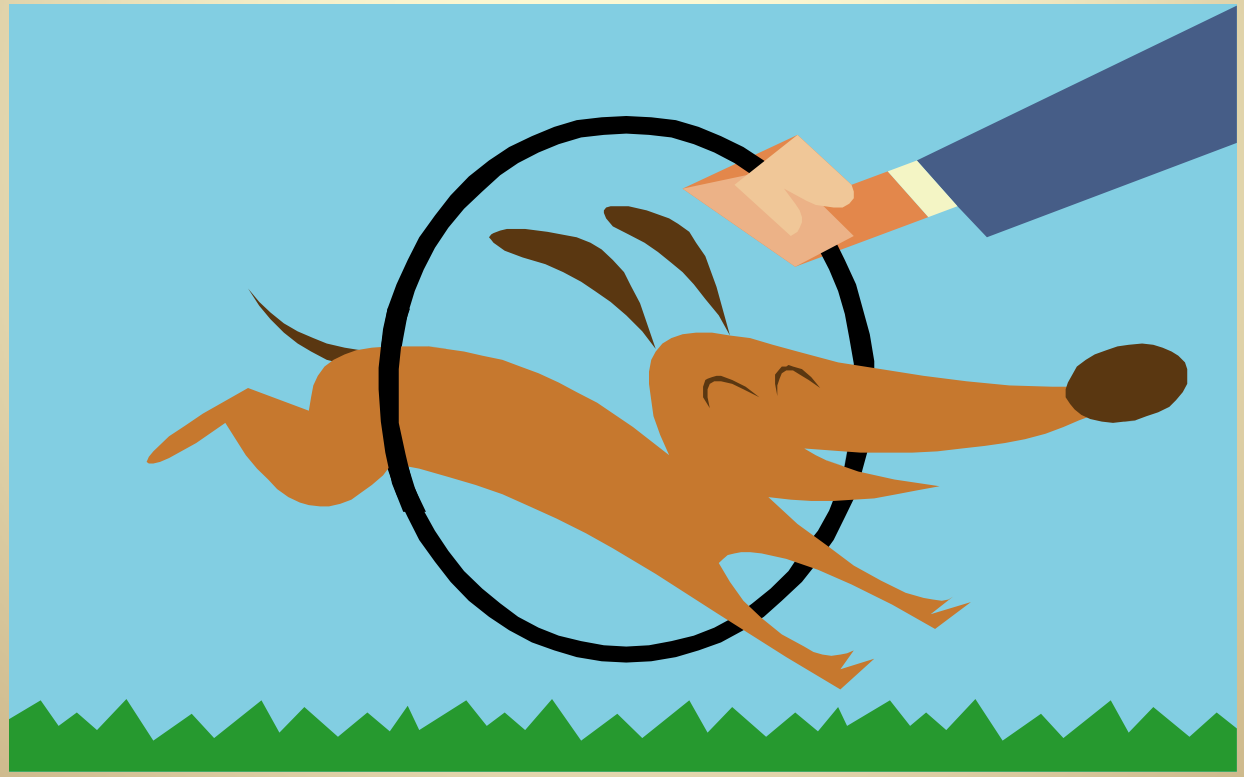




Spinning Ferris Wheel: Which Direction?
Rotating Mask Phenomenon and Interpretation Error

Reader Training

- Paramount importance of training the readers on expectations



Time to Review Images

- Standardization of time to review may be important

Software Functions

- Standardization of software -- can users:
  - Window/level
  - Zoom
  - Image invert
  - Perform high spatial frequency enhancement
  - Perform non-linear contrast modification

Pitfalls of Server Side Rendering

- Server side rendering vs. “thick client”

Saving Image Presentation State and Auditing Image Review Session

- Potential to audit entire image interpretation process or at least review how images were presented/saved is very important for clinical trials

Conclusion

- In addition to standardization of image acquisition, transmission, storage and analysis it is critical to understand the many challenges and pitfalls associated with image display which can have a major impact on medical image interpretation
- Understanding of these can have a major positive impact on the value of imaging as a means of following biomarkers for drug response and progression of disease

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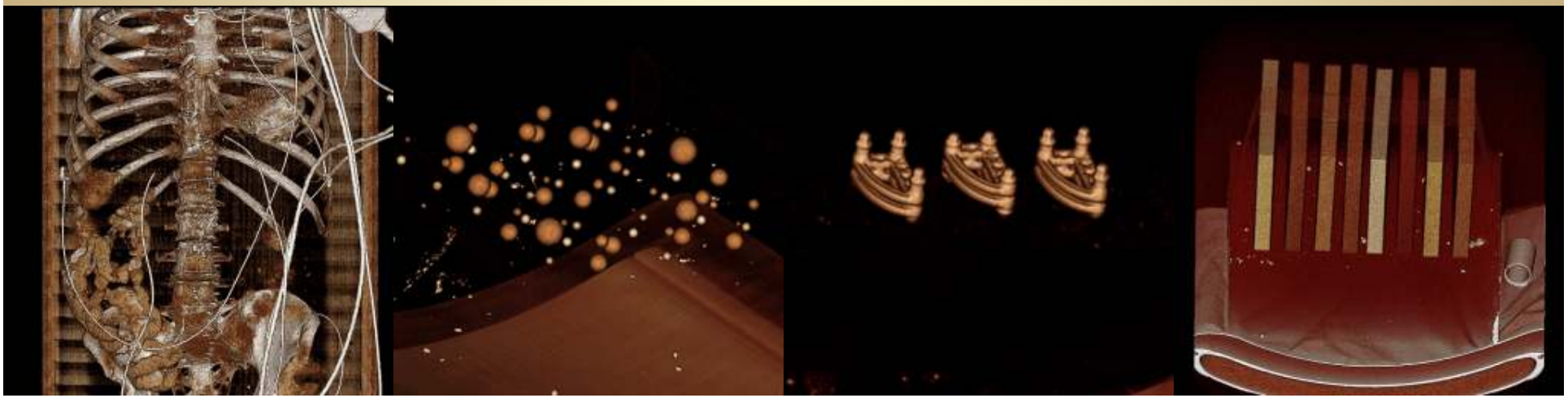
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