Session 7 Discussion

Herbert Y. Kressel, MD
Miriam H. Stoneman Professor of Radiology
Conflicts of Interest

No conflicts of interest reported.
Overall knowledge gap

• Are there medically meaningful adverse outcomes from retained GBCA and their metabolites?
Observational studies

• Exposure assessment –
  • Dose(s)
  • Contrast agent(s) utilized
  • Interval between exposure(s) and measurements
• Risk factor assessment before MRI exposure (and perhaps after MRI – for example radiation therapy of CNS tumor could affect findings in brain)
• Outcome assessment(s)
• Data validation
• Very rare adverse effect will need very large studies to find
“Retention” vs “symptoms”

- Identification of vulnerable patients
- Body symptoms/signs in CNS disease patients
- Neurological symptoms/signs in NON-CNS disease patients
- Gadolinium tissue topographic distribution (intra / extracellular in brain, skin, bone, liver etc.) – biosamples –
Prospective studies

• Normal healthy individuals vs. those with underlying conditions that might alter Gd entry to CNS/other organs

• ? Use of “convenience sample” for example of women undergoing contrast MR for breast cancer screening
Eligible Subjects Needing (Routine) Screening (Inclusion/Exclusion)

Data: age, sex, race, potential confounders (e.g., at-risk “low vs high”, disease?), timings of repeated GBCA (allowing assessment of frequency of GBCA), etc.

Data collection procedure such that dropouts can be minimized during follow-up

Pre-specified risk margin?

* CNTL1, CNTL2

Trial period – Trial Protocol

Sue-Jane Wang, OB/OTS/CDER/FDA

A Research Roadmap

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