CNT VOC sensor

- Factors impacting the reproducibility of the manufacturing method and final product
  - CNTs vary by batch, but there are recent advances in purifying and sorting (e.g., Fagan group at NIST)
  - Arrays of multiple sensors, with averaged readings, can also help address this
  - Huge clinical sample helps assure reliable statistical results
  - Mutiple CNT sources may be needed for different functionalizations
  - Need to quantify degree of functionalization; packing density, etc.; small changes make big difference in behavior
  - Functionalization tends to happen at defect sites; function of diameter
  - Control for external factors, such as what the test subject had for lunch before test
- Factors to consider when choosing materials (e.g., cost, purity, source)
  - Shorter nanotubes are more stable?
  - Some previous suppliers of reliable quality CNTs are no longer in business (e.g., SWENT)
  - Choice of molecules for functionalization; finding the right biomarkers for lung cancer is challenge
- The plan for testing, including field/test conditions, regulatory requirements, scope, etc.
  - Breath is consistent in temp, humidity.
  - Issue could be storage conditions, ambient environmental conditions during test
  - Development of test protocols, e.g., controlled test conditions, subject to FDA review

Team 4: Other Considerations (1 of 2)

- Factors impacting the scalability of the manufacturing method
  - Sterile/clean manufacturing conditions? Class 1000?
  - Consistent yield, which could be affected by surprising things, such as what mfg workers are eating/exhaling, if there are smokers on staff, etc.
  - Again, consistent source of quality CNTs – need QC at factory or you have to do it yourself – which rolls into cost of overall device.
- Limitations in terms of raw materials and processing technologies
  - Manufacturing and functionalization of CNTs is the key; from then on other issues can be addressed
  - Mass production of functionalized CNTs could be an issue
  - Reliability of foreign suppliers for raw materials can be subject to political considerations
- Manufacturing cost drivers for this technology
  - How many functionalized CNTs are we talking about on each panel?
- Remaining technical issues hindering commercialization of this technology
  - Innate reproducibility (or lack thereof) of test
  - Multivariate data analysis
  - Design (and cost) of clinical trials

Team 4: Other Considerations (2 of 2)

- Factors that will influence the decision to manufacture in-house vs. contracting out
  - Typically sensor maker would be buying, not making, CNTs. If the order is 500 g per year of CNTs, who is going to tool up to make that?
  - Supply chain is critical; if functionalized, need control of not only CNTs but also chemical you are going to use for functionalizations
  - Need to convince FDA of reliable, consistent manufacturing
  - QC from supplier, or in-house if supplier is not reliable or consistent
  - IP issues – outsourcing IP along with manufacturing?
- Life cycle considerations (e.g., device or effluent disposal)
  - Cost of incinerating aqueous solution of CNTs, organic solvents (for functionalization)
- Major safety concerns for manufacturing the sensor
  - Large-scale manufacturing could result in high exposure risks, vs lab-scale – exposure to solvents, catalysts, etc. Argument for out-sourcing manufacturing, where supplier has established safety protocols?
- Other (please specify)
  - Market is large, but FDA approval is high hurdle; alternative tests are also expensive and have risks (e.g., CT scan); a valid test that can find lung cancer early presents a very large opportunity