D2d Task force on non-diabetes outcomes

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Mission of Task Force

- Idea generating task force to identify non-diabetes outcomes that can be "easily" assessed in D2d
- Met 3 times since February 2016
  - Reviewed "gaps" in the literature
  - Reviewed data already being collected
    - AE reporting
    - Medication reporting
    - Data collected at visits
  - Discussed other ways to get non-diabetes outcome data

Conclusions

- Non-diabetes outcomes that we are reliably capturing:
  - Death
  - Musculoskeletal and connective tissue disorders
    - Fractures
  - Composite MACE
    - MI, Stroke, revascularization, CHF, etc
  - Composite CVD risk factors
    - ASCVD calculator and Reynolds risk calculator

Conclusions

- Unsure if we are adequately capturing:
  - Neoplasms
    - ?Differentiating cancer from benign in AE data
- Likely won't be able to capture well with D2d data:
  - Infections
  - Autoimmune disorders
  - Asthma
  - Pain
  - Depression/mood

Suggested next steps

- Already planned for D2d:
  - Measure 25OHD, cholesterol profile, insulin, CRP at BAS/M12/M24 in first 1200 participants who complete M24 visit
- Possible additions to this plan:
  - Add other biomarkers (e.g. circulating microRNA's, IL-6) to serum testing being done on first 1200 participants?
  - Also run tests on urine samples (e.g. albumin) on first 1200 participants?

Possible additions

- Mood/depression:
  - Add 2 questionnaires (1 QOL [SF12] and 1 mood [TBD]) to 24 month visit?
    - *Note: No baseline data available*
- Cancer/pre-cancer:
  - Obtain colonoscopy reports from participants?
  - Obtain mammography reports from participants?