W3C Life Sciences: Clinical Observations Interoperability: EMR + Clinical Trials

Use-case for EMR + Clinical Trials Interoperability

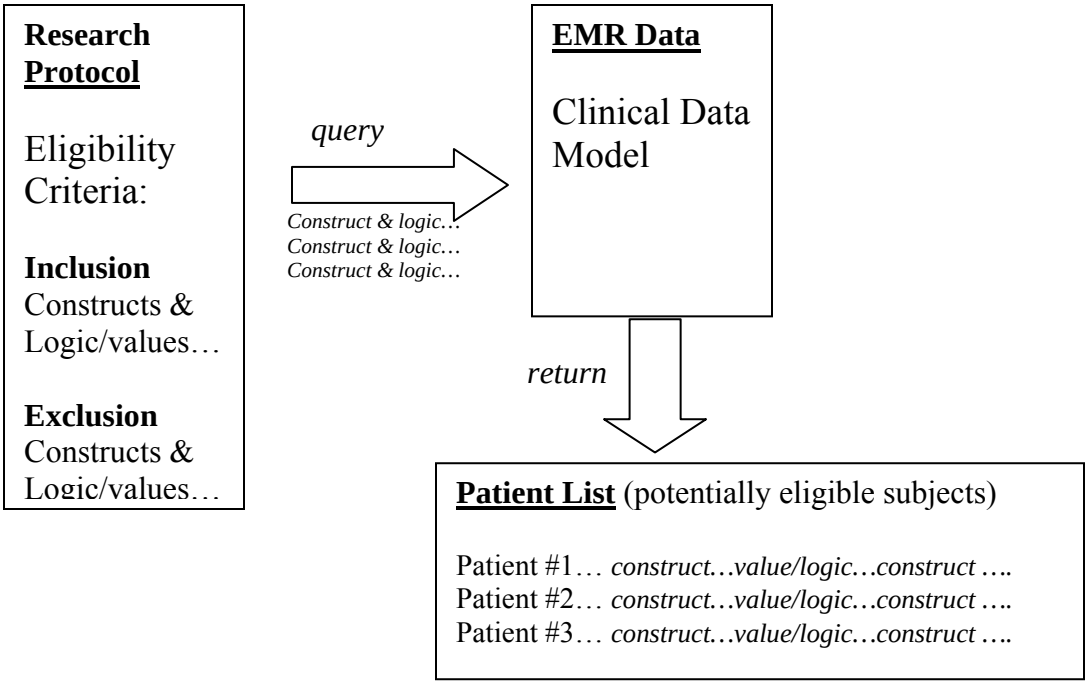
Background:
The key issue is to investigate whether some of the data collected in a clinical encounter can be re-used in the context of a clinical study.

Constructs of particular interest to the W3C working group from July 2007 include:

Vital Signs
Chemistry Panel (Labs)
Problems and Diagnoses
Imaging Biomarker
C-Reactive Protein

Scenario:
Examine patient data from EMR, and compare with protocol eligibility information to screen for potential research subjects or to estimate possible # of potential research subjects.

Approach: Have a protocol in mind first, scan EMR records with that eligibility criteria in mind.



Examples of Trials and Eligibility Criteria from ClinicalTrials.gov

Trial #1:

Prophylactic Irradiation to the Contralateral Breast for BRCA Mutation Carriers Undergoing Treatment for Breast Cancer

http://www.clinicaltrials.gov/ct/show/NCT00496288?order=2

Eligibility

Ages Eligible for Study: 30 Years - 90 Years, Genders Eligible for Study: Female
Criteria

Inclusion Criteria:

1. Female patient diagnosed with stage I-III breast cancer (AJCC 6), undergoing breast irradiation as part of her adjuvant therapy.
2. The patient must be a carrier of a deleterious mutation in BRCA 1/2.
3. Age above 30 years.
4. The patient may receive any regimen of adjuvant chemotherapy, according to the treating physician. All cycles of chemotherapy must be completed at least 3 weeks prior to the start of radiation therapy.
5. The patient may be treated with hormonal therapy before, during or after study entry, according to the guidelines of her treating center.
6. The patient must have negative gadolinium based MRI of the contralateral breast, no more than 6 months prior to study entry.
7. The patient refused prophylactic contralateral mastectomy.
8. The patient is aware that subsequent breast cancer in the irradiated breast will probably mandate mastectomy.
9. The patient consent for contralateral prophylactic irradiation. -

Exclusion Criteria:

1. Metastatic breast cancer.
2. Previous irradiation of the breast or chest wall.
3. Pregnancy.
4. No concurrent chemotherapy is allowed
5. Patients with active connective tissue diseases are excluded due to the potential risk of significant radiotherapy toxicity.
6. Patients who are unable to lie on their back and raise their arms above their heads in the treatment planning position for radiotherapy are excluded -

Trial #2:

Breast Density, Hormone Levels, and Anticancer Drug Levels in Women With Invasive Breast Cancer Who Are Receiving Exemestane or Anastrozole

http://www.clinicaltrials.gov/ct/show/NCT00316836?order=4

Eligibility

Ages Eligible for Study: 18 Years and above, Genders Eligible for Study: Female
Criteria

DISEASE CHARACTERISTICS:

- Histologically confirmed invasive breast cancer
- Completely resected disease
- One intact, noncancerous breast with no prior breast surgery in that breast except breast biopsy
    - Mammogram available taken within 12 months prior to enrollment that includes side- and top-down views of the intact, noncancerous breast

- Estrogen receptor- and/or progesterone receptor-positive tumor

PATIENT CHARACTERISTICS:

- Female
- Postmenopausal
- Agrees to retrieve and digitize mammograms taken prior to registration (within 12 months prior to study entry) and at approximately 1 and 2 years post-registration to this study
- Agrees to have an additional blood banking specimen drawn at the same time as pre-treatment specimens are drawn for parent protocol CAN-NCIC-MA27
- Agrees to have blood sample taken at 12 months post-registration on this study

PRIOR CONCURRENT THERAPY:

- See Disease Characteristics
- More than 6 months since prior hormone replacement therapy, oral contraceptives, tamoxifen, raloxifene, other selective estrogen-receptor modulators, or gonadotropin releasing-hormone analogues before pre-registration mammogram

Trial #3:

Changes in Breast Density and Breast Cancer Risk in Women With Breast Cancer and in Healthy Women

http://www.clinicaltrials.gov/ct/show/NCT00445445?order=13

Eligibility

Ages Eligible for Study: 50 Years and above, Genders Eligible for Study: Female

Accepts Healthy Volunteers

Criteria

DISEASE CHARACTERISTICS:

- Meets 1 of the following criteria:
    - Patient at the University Hospitals Breast Center and primary care clinics within the University Hospitals system AND meets the following criteria:
        - Histologically confirmed breast cancer that was diagnosed between the years 2002-2004
            - Known tumor stage
    - Healthy participant who is receiving routine medical care (e.g., screening mammograms) at the University Hospitals Health System
- Underwent ≥ 4 prior screening mammograms at the Breast Center since 1994
- No known carriers of BRCA1 or BRCA2 genes
- Hormone receptor status:
    - Known estrogen and/or progesterone receptor status

PATIENT CHARACTERISTICS:

- Female
- Menopausal status not specified
- No breast implants

PRIOR CONCURRENT THERAPY:

- Not currently taking tamoxifen citrate, raloxifene, or aromatase inhibitors

Future Steps:
Approve overall scenario.
Determine which constructs of most interest.
Identify protocol(s) with those information types.
Landen comment on relationship of CDISC standards to this use case…. (CDISC Protocol Representation Standard..?)