**Purpose:** 18F - OpenFDA AE Transparency API Prototype

**Meeting Notes:**

Potential use groups for the prototype:

1. Consumers/Patients/Care Givers;
2. Researchers including Legal Professionals;
3. Physician and Medical Professionals. FDA OpenFDA website mentions the above two user classes, and does not specifically note Physician and Medical Professionals as intended users. For purposes of the prototype it does seem appropriate to create pages on the site in the prototype that might be tailored to other than the first two user classes.

**Consumers/Patients/Care Givers**

The group may focus most on drug and device products for which they, or someone in their care, have some experience with. Although both drug and device products may eventually be options for this user class to select, limiting this option to drug products might be sufficient for purposes of the prototype. Device products may be highlighted for the second use class of researchers and legal professionals.

In the case of drug products interest may include information on the adverse reactions reported, the seriousness of reactions, and information pertaining to FDA enforcement actions related to the product drug or device.

For purposes of illustrating capability in a prototype presenting users with either a form/field to enter a product name should be available. In addition, users may prefer drop down list form which to select a product name. For purposes of illustrating capability, perhaps lists could be presented pre-populated with product names of the 10-15 most commonly prescribed drugs in one of three or four disease category., i.e. cardiovascular; diabetes; asthma; or psychiatric. Cancer drugs might be too complicated because the type of treatment drug varies based on cancer type making multi-level selection criteria complicated and requiring additional programming logic.

Here are some of the most common prescribed drugs for the disease categories suggested for the prototype:

Cardiovascular:

* Lipitor
* Plavix
* Crestor
* Zocor
* Norvasc
* Lisinopril
* Lescol
* Livalo
* Pravachol
* Mevacor

Source: <http://www.webmd.com/news/20110420/the-10-most-prescribed-drugs>

Diabetes:

* Glucophage
* Actos
* Amaryl
* Levemir
* Glucotrol
* Tolazamide
* Glyset
* Precose
* Victoza
* Januvia

Source: <http://www.fiercepharma.com/special-reports/10-top-selling-diabetes-drugs-2012?page=0,2>

Asthma:

* Advair
* Singulair
* Aerobid
* Asmanex
* Albuterol
* Proventil
* Ventolin
* Brovana
* Foradil
* Accolate
* (Avandia)

Source: <http://www.ct.gov/dph/lib/dph/hems/asthma/pdf/pt._med_ed._sheet.pdf>

Psychiatric

* Abilify
* Adderall
* Aventyl
* Seroquel
* Xanax
* Zoloft
* Celexa
* Prozac
* Cymbalta
* Ativan

Source:

<http://psychcentral.com/lib/top-25-psychiatric-medication-prescriptions-for-2013/>

Once selected the query should return descriptions of the adverse reactions ranked by frequency of mention, and also by severity. This could be combined to return both the frequency and the severity, giving the user the option to toggle between frequency and severity, if possible.

Also, if possible, it would be informative to present any FDA enforcement action related to any drug. For the lists of drugs above it is unlikely a query will return data as these drugs are all currently actively marketed in the United States. Including Avandia in the Diabetes list might show FDA enforcement action since the drug was removed from markets outside the US and has a number of serious adverse reactions.

**Researchers including Legal Professionals**

The group may focus most on drug and device products for which they, or someone in their care, has experience with an adverse reaction. Although both drug and device products may eventually be options for this user class to select, limiting this option to device products might be sufficient for purposes of the prototype as drugs are illustrated in the Consumers/Patients/Care Givers user class. Device products may be highlighted for the second use class of researchers and legal professionals looking for information on device effectiveness, durability, and adverse reactions. The query set might be similar to the logic driving drug question – that is, return adverse even descriptions by device name, patient demographic, and note results according to severity. For device events, the type of review protocol requested by manufacturers, and granted by FDA, is a significant factor in litigation involving adverse reactions. Enforcement action by FDA might also be queried and returned if any records are found.

As is the case of drug products, interest in device experience may include information on the adverse reactions reported, the seriousness of reactions, and information pertaining to FDA enforcement actions related to the product drug or device.

For purposes of illustrating capability in a prototype presenting users with either a form/field to enter a product name should be available. In addition, users may prefer drop down list form which to select a product name. For purposes of illustrating capability, perhaps lists could be presented pre-populated with product names of the 10-15 most commonly used devices in one of three or four application category., i.e. cardiovascular (drug eluding stents, cardiac pacemakers); joint replacement device (hip, knee, ankle); Urogynecologic Surgical Mesh Implants;

From the Global Unique Device Identification Database (GUDID) <http://accessgudid.nlm.nih.gov>. a pick list might be made to illustrate the search capability for the prototype. The **Researchers including Legal Professionals** user class might be most interested in adverse reaction description and FDA enforcement action.

**Physician and Medical Professionals**

* Focus on indication
* AE description
* Seriousness

**End of Session**