# Database Schema

This document describes the schema of the database as required by the DILI protocol.

## Term Definitions

* String: text variable
* Boolean: yes/no variable
* Float: non-integer real number variable

## Users

This table will contain list of users of the app and their roles

|  |  |  |  |
| --- | --- | --- | --- |
| Field | Type | Description | Constraints |
| unique | String | Unique Identifier | Unique to every user |
| name | String | User's Name | Unique to every user |
| institution | String | User's Institution | {AKUH, JPMC, CHK, LNH, ASH, ZH} |
| role | String | User's Role | {admin, entrant, analyst} |

#### Consideration

* role
  + Admin will have privileges to read from registry, write to registry, modify registry, and add users
  + Delegate will have privilege to add entrants
  + Entrant will have privilege to write to registry via app only
  + Analyst will have privileges to read from registry via dedicated online portal
  + Users can have multiple roles
    - e.g. a physician can be given entrant role to add suspected cases of DILI as well as delegate role to invite other physicians to the program
  + Users will be added only after review by Dr. Shahab Abid
    - Optionally requirement for electronic countersignature can be enforced

## Patient Characteristics

|  |  |  |  |
| --- | --- | --- | --- |
| Field | Type | Description | Constraints |
| unique | String | Unique Identifier | Unique to every patient |
| name | String | Patient’s Name | none |
| age | Number | Patient’s Age | Greater than 2 |
| gender | String | Patient’s Gender | {male, female} |
| consent | Boolean | Has patient given consent | none |
| entrant | String | ID of physical entering data | none |
| entrydate | Date | Date of data entry | none |

#### Considerations

* age
  + How precise do we want to be about age? Nearest year or nearest month?

## Dili Episode

### Suspected Drug

|  |  |  |  |
| --- | --- | --- | --- |
| Field | Type | Description | Constraints |
| drug | String | Drug suspected to have caused DILI | Alphabets only |
| dose | Float | Administered dose of the drug suspected | none |
| doseunit | String | Unit of dose of the drug suspected | {milligrams, micrograms} |
| indication | String | Indication for which the suspected drug was administered | none |
| rechallenge | Boolean | Was patient re-challenged with the suspected drug? | none |
| rechallengeres | String | What was result of re-challenge? | ??? |

#### Considerations

* rechallengres
* Can this variable be further codified? Are there specific signs and symptoms we are looking for during re-challenge?
  + E.g. rash, fever, hepatomegaly, change in laboratory values?

### History

|  |  |  |  |
| --- | --- | --- | --- |
| Field | Type | Description | Constraints |
| onset | Date | Date of onset of symptoms | greater than 3 months prior to record entry |
| icteric | Boolean | Was patient visibly icteric on presentation | none |
| nausea | Boolean | Was the patient nauseated on initial presentation | none |
| vomiting | Boolean | Was the patient vomiting on initial presentation | none |
| anorexia | Boolean | Was the patient anorexic on initial presentation | none |
| abdpain | Boolean | Did the patient complain of abdominal pain on initial presentation | none |
| darkurine | Boolean | Did the patient complain of dark colored urine on initial presentation | none |
| pruritis | Boolean | Did the patient complain of itching on initial presentation | none |
| rash | Boolean | Did the patient complain of rash on initial presentation | none |
| fever | Boolean | Did the patient complain of fever on initial presentation | none |

#### Considerations

* fever & rash
  + Is there a need to include a separate variable for fever and rash in the history section?
  + Is there a significance to fever and rash reported by the patient but is not present on examination at initial presentation?

### Physical Examination

|  |  |  |  |
| --- | --- | --- | --- |
| Field | Type | Description | Constraints |
| fever | Boolean | Did the patient have documented fever on initial examination | none |
| rash | Boolean | Did the patient have rash on examination on initial presentation | none |
| icteric | Boolean | Was the patient visibly icteric on examination on initial presentation | none |
| hepatictender | Boolean | Did the patient have hepatic tenderness on initial examination | none |
| stigmata | Boolean | Did the patient have one or more stigmata of CLD on initial presentation | none |

#### Considerations

* Stigmata
  + Do we need to further codify "stigmata" into yes/no responses?
    - E.g. spider angiomas, hepatomegaly, pedal edema
  + Or should we define "stigmata" as presence of two or more stigmata of CLD on clinical examination?

### Medical History

|  |  |  |  |
| --- | --- | --- | --- |
| Field | Type | Description | Constraints |
| hf | Boolean | Does the patient have heart failure | none |
| hypotension | Boolean | Is the patient hypotensive on presentation | none |
| septic | Boolean | Is the patient septic on initial presentation | none |
| tpn | Boolean | Did the patient receive TPN immediately prior to presentation | none |
| hepB | Boolean | Does the patient suffer from Hepatitis B | none |
| hepC | Boolean | Does the patient suffer from Hepatitis C | none |
| alcohol | Boolean | History of alcohol abuse | none |
| comorbid | List | Known hepatic co-morbidities | {Hep C, Hep B, HCC, hemochromomatosis, Wilson’s } |

#### Considerations

* tpn
  + Will there be limit to how recently TPN was given to qualify as yes?
  + According to some journals, TPN components have various half lives from 12 hours to 1 month; is 3 months a reasonable cut off?
* hepC
  + Do we need to differentiate between Hep C undergoing treatment and Hep C completed treatment?

### Drug History

|  |  |  |  |
| --- | --- | --- | --- |
| Field | Type | Description | Constraints |
| medhx | String | What medicines has the patient taken 3 months prior to initial presentation | Alphabets only |
| medhxdose | Float | What was the dosage of these medications | greater than 0, milligrams |
| medhxduration | Number | How long did the patient take these medications | Number only, months |
| pastrxn | String | Has the patient previously been exposed to this drug | none |

### Laboratory Tests on Initial Presentation

|  |  |  |  |
| --- | --- | --- | --- |
| Field | Type | Description | Constraints |
| date | Date | Date on which patient's initial labs were drawn | greater than 1/1/2018 |
| bilirubin | Float | Patient bilirubin on initial presentation | non-negative |
| ast | Float | Patient’s AST level on initial presentation | non-negative |
| alt | Float | Patient’s ALT level on initial presentation | non-negative |
| alkPhos | Float | Patient’s Alkaline Phosphatase level on initial presentation | non-negative |
| INR | Float | Patient’s INR on initial presentation | non-negative |
| antiHAVIgM | Boolean | Anti-HAV IgM reactive on initial presentation | none |
| antiHBcIg | Boolean | Anti-HBc Ig reactive on initial presentation | none |
| HBsAg | Boolean | HBsAg reactive on initial presentation | none |
| antiHCVIg | Boolean | Anti-HCV Ig reactive on initial presentation | none |
| HCVrna | Boolean | HCV RNA reactive on initial presentation | none |
| ANA | Boolean | ANA reactive on initial presentation | none |
| biopsy results | Image | Upload picture of biopsy results report | less than 100KB |

#### Considerations

* Do each of these lab values need separate date fields
  + Will doing that make it harder for physicians to fill out the mobile proforma?

### Past Laboratory Records

|  |  |  |  |
| --- | --- | --- | --- |
| Field | Type | Description | Constraints |
| astprior | Float | Patient’s most recent AST level prior to initial presentation | none |
| astpriordate | Date | Date of Patient’s most recent prior AST level | greater than 1/1/2018 |
| altprior | Float | Patient’s most recent ALT level prior to initial presentation | none |
| altpriordate | Date | Date of Patient’s most recent prior ALT level | greater than 1/1/2018 |
| alkphosprior | Float | Patient’s most recent Alkaline Phosphatase level prior to initial presentation | none |
| alkphospriordate | Date | Date of Patient’s most recent prior Alkaline Phosphatase level | greater than 1/1/2018 |
| inrprior | Float | Patient’s most recent INR prior to initial presentation | none |
| inrpriordate | Date | Date of Patient’s most recent prior INR | greater than 1/1/2018 |

### Follow-up Laboratory Records

|  |  |  |  |
| --- | --- | --- | --- |
| Field | Type | Description | Constraints |
| bilirubinfup | Float | Follow up bilirubin | non-negative |
| bilifupdate | Date | Date on which follow up bilirubin was drawn | greater than 1/1/2018 |
| altfup | Float | Follow up ALT | non-negative |
| altfupdate | Date | Date on which Follow up ALT was drawn | non-negative |
| alkPhosfup | Float | Follow up Alkaline Phosphatase | non-negative |
| alkPhosfupdate | Date | Date on which follow up Alkaline Phosphatase was drawn | greater than 1/1/2018 |
| INRfup | Float | Date on which follow up bilirubin was drawn | non-negative |
| INRfupdate | Date | Date on which follow up bilirubin was drawn | greater than 1/1/2018 |