# Introduction

Currently called SyntheticMass but need a new name as it grows into a full HIE (MA HIE or Open Source HIE aka OSHIE)

# Sources

<https://www.paehealth.org/images/pdf/PA_eHealth_Appendix_M_-_Use_Cases.pdf>

<http://calhipso.org/documents/HIE_Toolkit_06.30.2013.pdf>

MassChallenge HIE Infrastructure Schulz edit 6-16-161.docx by Schulz, Kris

# Milestones

## Mass Challenge (starting October 2016)

The Mass Challenge runs from October 2016 to February 2017. See <http://masschallenge.org/>.

Offer syntheticmass.mitre.org populated with 7 million synthetic patients statistically matching the real residents of MA and supporting the following initial functionality:

**Entrepreneur/Vendor Use Cases Available:**

5.2.1 Download Synthetic Patients by Criteria in Specified Format

5.2.2 Integration Test of a FHIR client using Synthetic Data

5.2.3 Integration Test Direct Sending using Synthetic Data

5.2.4 Integration Test Direct Receiving using Synthetic Data

5.2.5 Search Synthetic Patients

5.2.6 View Synthetic Patient

**Public Health Official Use Cases Available (using synthetic data for demonstration):**

5.3.1View Dashboard Summarizing Patients in MA (immunizations, diseases)

**Researcher Use Cases Available (using synthetic data for demonstration):**

5.4.2 Download Raw Data in CSV format

5.4.4 View Maps

## SyntheticMass (?)

Completion of the Entrepreneur/Vendor use cases should complete the basic functionality of SyntheticMass.

## MA HIE v1

Initial cut of use cases for patient, provider, researcher, entrepreneur/vendor, and administrator.

In order to support all use cases on a common server instance, we need to separate out synthetic patients and real patients (See 6.1 Support Multiple Patient Lists). FHIR does offer a compartment concept that can be named and has a boolean attribute labelled “experimental” that indicates the compartment definition is authored for testing purposes. It also includes a publisher such that the synthetic data can be attributed to MITRE Synthea. It also includes a requirements attribute that can be used to describe the scope and usage that the compartment definition was created to meet. Predefined compartment types are focused around isolating the data for a particular resource (e.g., a single patient), but potentially it could be used for a list of patients and their associated data as well?

Example of using a compartment in a search:

GET [base]/[Compartment]/[id]/[type]{?[parameters]{&\_format=[mime-type]}}

See <http://hl7.org/fhir/2016May/compartmentdefinition.html> and <http://hl7.org/fhir/2016May/http.html#vsearch>.

Of course, multiple FHIR service instances with separate databases could be used as well. The web application would then need to support multiple FHIR endpoints.

## MA HIE v2

Complete use cases for patient, provider, researcher, entrepreneur/vendor, and administrator. Initial cut of public health official, guardian, guest, and payer use cases.

## MA HIE v3

Functionally complete

## National HIE Test Bed (?)

TBD

# Actors

## Administrator

Users who administer the SyntheticMass/HIE site will require access to administrative functions on the site

## Entrepreneur/Vendor

Vendors implementing new systems and technologies must interoperate with other vendors and require data for testing their systems. These users are referred to as entrepreneurs.

## Guardian

A patient will often have assigned guardians who are responsible for their medical care and therefore should have access to the patient’s health record.

## Guest

A user wanting to learn more about SyntheticMass/MA HIE should be able to access the site and learn about it without establishing an account.

## Patient

A patient receives health care from providers.

## Payer

Payers are insurance providers. Payers sell insurance to patients and pay for patient care to providers.

## Provider

A provider provides care to patients and gets paid for those services by payers. Providers also purchase and use systems and software from entrepreneurs.

## Public Health Official

A public health official is someone representing a government health agency.

## Researcher

Researchers are professionals who use medical data to expand medical knowledge and hopefully improve care for patients in the future.

## Trial User

A trial user is someone showing the system to other people or a person directly trying out the system.

# Use Cases

## Missing Functionality?

1. Blue Button
2. ADT Tracking
3. ADT Alerts
4. Query-based Exchange
5. eHealth Exchange
6. EMS Care Coordination
7. Data Analytics
8. Patient de-duplication
9. May need additional actors for prospective providers/entrepreneurs/payers/researchers to try the HIE out?

## Entrepreneur/Vendor (secure web access)

### Download Synthetic Patients by Criteria in Specified Format

An entrepreneur/vendor will define criteria against synthetic patients and then download the matching ones to a specified format (CCDA, FHIR, or SHR implementation format).

1. User chooses to download synthetic patients
2. System displays criteria options
3. User defines criteria (demographics, conditions, medications, locations, providers, and dates)
   1. User select a previously saved set of criteria
   2. User saves current criteria
4. System displays summary of matching patients (count, geographic distribution, ?)
   1. User chooses to view list of synthetic patients
   2. System displays list of synthetic patients matching criteria
5. User chooses an export format (CCDA, FHIR, SHR implementation format(s))
6. System creates export file in requested format containing matching patients and allows user to save it to their local machine

### Integration Test of a FHIR client using Synthetic Data

An entrepreneur/vendor can test a FHIR client they are building against the SyntheticMass FHIR server with synthetic data.

1. FHIR client makes FHIR calls to system
2. System handles requests and responds per FHIR specification

### Integration Test Direct Sending using Synthetic Data

An entrepreneur/vendor can test their Direct implementation by sending and receiving Direct messages from SyntheticMass. Any data sent are synthetic.

1. User sends a DIRECT e-mail to SyntheticMass
2. System reads and accepts the e-mail and its content (CCDA format).
3. System inserts the provided patient data

NOTE: early versions may not merge Direct data with FHIR data

### Integration Test Direct Receiving using Synthetic Data

An entrepreneur/vendor can test their Direct implementation by telling SyntheticMass to send it

### Search Synthetic Patients

An entrepreneur/vendor can define criteria and view a list of matching synthetic patients.

### View Synthetic Patient

An entrepreneur/vendor can view the health record of a synthetic patient.

### Test Interoperability of FHIR client using Synthetic Data

An entrepreneur/vendor can test their FHIR client by executing a defined compliance test suite using SyntheticMass as the server-side that will validate the client requests are correct and then return expected results as defined in the test suite.

1. FHIR client makes each predefined call from test suite
2. System responds with response
3. FHIR client validates that response is correct per test suite

### Test Interoperability of FHIR server using Synthetic Data

An entrepreneur/vendor can test their FHIR server by initiating the client compliance test suite via SyntheticMass. SyntheticMass will then proceed to invoke each test case in the suite and validate the responses.

1. User initiates test suite for a provided FHIR service endpoint
2. System executes test suite and verifies each response and presents user with results

### Test Compliance of a Standard Health Record Instance

An entrepreneur/vendor can provide an instance of a Standard Health Record and SyntheticMass will assess its compliance and provide a report.

1. User provides an instance of a Standard Health Record
2. System identifies the format and version of the Standard Health Record provided and validates that the instance complies with the standard
3. User acknowledges that the instance was in compliance

## Public Health Official (secure web access)

### View Dashboard Summarizing Patients in MA (immunizations, diseases)

A public health official can see a dashboard summarizing the health of MA residents. Trending conditions, high volume locations, and other metrics will be shown.

### Highlight Changes in Citizen Health Status

### View Dashboard of Interoperability and Adoption Status

### View Activity Metrics

### Manage Metrics

Create, view, update, and delete metrics based on patient records. Metrics can be promoted to the MA Dashboard. See 5.3.1 View Dashboard Summarizing Patients in MA (immunizations, diseases).

## Researcher (secure web access)

### Analyze Health Data

A researcher can analyze the aggregated health records by defining queries against the data. Specific patient identifying information will never be returned.

### Download Raw Data in CSV format

A researcher can query the patient data and download the results in CSV format. Specific patient identifying information will never be returned.

### Manage Maps

A researcher can create, update, and delete maps that they own. Maps created by a researcher are private unless explicitly marked as public.

### View Maps

A researcher can view their maps or any other public maps.

### Manage Graphs

Create, update, and delete defined graphs. Graphs can be public or private.

### Manage Notifications

Set up standing queries that define conditions under which researcher should be notified; e.g., a certain statistic passes a threshold value.

### Receive Notification

The researcher receives notifications when conditions that they define occur. See Manage Notifications. Notifications should exist on the site but ideally can be sent as an e-mail or a text message as well (with no PHI).

## Patient (secure web and mobile access)

### View My Health Record

Patient can view their own Health Record on the site or can download it in an encrypted, password protected format allowing them to provide their current Health Record to a provider without access.

### View Audit Log of Accesses of My Health Record

A patient can view all accesses of their health record. Should they have a way to question an access?

### Update My Health Record

Depending on data being updated, update may occur directly (e.g., patient address), require approval from provider (e.g., adding an encounter that occurred while in a different country), or not be allowed (update an existing encounter)

### Manage Provider-Assigned Actions

Add comments, status updates, and results to provider-assigned actions.

### Identify Issues in My Health Record

Patient can add comments/questions to their health record including targeted questions to specific providers.

### Control Access to My Health Record

Providers/Payers can request access and patients can change rules for who has access and to what parts of their record.

## Provider (secure web and mobile access)

### View Patient Record

Provider must search for desired patient using patient identifiers. Provider may not have access to requested patient. View it on the site or have it send to their DIRECT e-mail address or download it in a specific format. Portions of record may not be visible to provider. Alternate course is when they don’t have access to the record or to a portion of it and they can request it.

### Summarize Patient Record

A provider can just see key data within an SHR to summarize a patient quickly.

### Update Patient Record

A provider can update a patient’s record including adding new encounters, lab results, conditions, etc.

### Create Action for Patient

A provider can create an action for a patient which may be to make an appointment, weigh themselves once a week and record it in their SHR, log what they eat for a period of time, go get blood taken at a local lab, etc.

### Update myself in Provider Directory

A provider can update their direct e-mail address, regular e-mail address, phone numbers, street address(es), and other contact information in the provider directory. They can also upload their certificates.

### Look up another Provider in Provider Directory

A provider can look up another provider in the provider directory in order to contact them (e.g., send a referral or lab results via Direct).

### Manage My Notification Rules

Control what types of updates cause notifications (e.g., emergency room encounter) and the priority associated with the notification. Priority may also dictate notification mechanism (message on site at next login, e-mail, text message?)

### Receive Notification that Patient Was Updated

A provider can define criteria under which patient updates will notify them and how they will be notified. For example, updates to any patient that they are defined as the primary care physician may result in an e-mail being sent to them. For another example, if any of their patients with a certain condition have an admit event, then the provider is notified via text message.

### Dispose of Potential Issues

The provider views potential issues identified by a patient, guardian, or another provider and disposes of them. Only providers with the ability to update the part of the patient record that the issue is associated with can address the issue.

## Guardian (secure web and mobile access)

### View a Ward’s Patient Record

A guardian can view any of their wards’ patient records.

### Update a Ward’s Patient Record

A guardian can update some data in a ward’s patient record, and can request that other parts of it be updated as well.

### Identify Issue in a Ward’s Health Record

A guardian can identify a particular piece of data within a ward’s patient record that they think is incorrect and should be fixed.

## Payer (secure web access)

### View Subscriber’s Health Record

Payer must search for desired patient using patient identifiers. Payer may not have access to requested patient. View patient on site or have it sent to a DIRECT e-mail address or download it in a specific format. Part of the record may not be visible to payer.

### View Statistics Across Subscribers

## Guest (web and mobile access)

### Learn about SyntheticMass

A guest should be able to read about SyntheticMass to learn about it and the SHR.

### Register with Site

A guest can request a login on SyntheticMass for a particular role (e.g., patient).

### View Public Health Data

A guest can view public health data which consists of some aggregated statistics about all residents.

### View Standard Health Record Specification

A guest can get more information about the SHR including specifications.

## Administrator (secure web access)

### Manage Users

An administrator can add, view, update, and delete users from SyntheticMass.

### Lock/Unlock User Accounts

An administrator can lock or unlock user accounts.

### Archive Patient Data

An administrator can choose to archive some patient-related data based on criteria. Archived data is removed from the primary tables and must be de-archived before it can be accessed again.

### De-archive Patient Data

An administrator can put archived data back into the primary data store such that it is accessible again.

### Backup Data

An administrator can initiate a backup or schedule periodic backups of data owned by the system. Any backed up data must be protected to ensure its privacy, integrity, and that only authorized users can access it.

### Restore Data from Backup

An administrator can choose to restore data from backup into the active system.

### Log an Active User Out

An administrator can choose a currently logged in user and kick them out of the system.

### See Login Attempts

An administrator can view a log of login attempts (successful and unsuccessful).

### Notify if Failed Login Attempts Exceeds a Threshold

An administrator can receive a notification if failed login attempts from a single IP address exceed a certain number in a certain timeframe.

## Trial User

### Use the System as if Logged in as a Selected Role

A trial user can choose a role (e.g., patient, provider, researcher, etc.) and use the system as if they were logged in as a user of that type. All data access will use the synthetic data.

## Shared (Leveraged to support other use cases)

### Login

Any user (except guest) should be able to login to their account by authenticating with SyntheticMass.

### Provide Feedback

Any user can provide feedback on SyntheticMass including potential enhancements.

### Request Support

Any user should be able to request support with SyntheticMass if they are having trouble.

### Forgot Username and/or Password

Any user can indicate that they forgot their username and/or password.

### Change Password

Any user can change their password.

### Manage My Preferences

Any user can setup certain preferences only affecting their use of SyntheticMass.

# Non-Functional Requirements

## Support Multiple Patient Lists

SyntheticMass needs to support the synthetic patient list plus at least one real (and potentially multiple) patient list.

## Support Infrastructure

Need software to log and track the disposition of support requests which may include requested enhancements and defects.

Need a process for disposing of support requests, enhancement requests, and defects. A Change Control Board or some other mechanism for prioritizing items will be required.

## Security

The HIE site must use TLS/SSL for privacy and require user authentication (2 factor for some roles and/or functions?)

Data at rest must be encrypted as well?

## HIPAA Compliance

## Section 508

Accessibility requirements

## Resilience

Any security breaches must be limited in scope; gaining access to one patient’s record should never allow access to others

# Glossary

## ADT = Admit, Discharge, Transfer

Acronym for three common events for patients – being admitted to a hospital or facility, being discharged from a hospital or facility, and being transferred between medical facilitities.

## ARRA = American Recovery and Reinvestment Act

The American Recovery and Reinvestment Act of 2009 is an economic stimulus package. ARRA includes HITECH (see HITECH).

## Blue Button

As America’s health care system rapidly goes digital, health care providers, insurance companies and others are starting to give patients and consumers access to their health information electronically through the “Blue Button”. [Source: <https://www.healthit.gov/patients-families/faqs/what-blue-button>]

## CCDA (or C-CDA) = Consolidated-Clinical Document Architecture

Health Level 7 standard for meeting 2014 Edition HER Certification Criteria in support of Meaningful Use Stage 2.

## CSV = Comma-Separated Values

Format for tabular data in a text file where each record is a line and each cell is separated by commas

## Direct

Standard for secure electronic exchange of healthcare information

## DSTU = Draft Standard for Trial Use

Version naming scheme used for FHIR standard. DSTU3 is the latest version which is the Draft Standard for Trial Use 3. See also STU as DSTU3 is being renamed STU3. DSTU/STU releases are precursors to the first official 1.0 release. Source: <http://hapifhir.io/>

## EHR = Electronic Health Record

An electronic health record provides all medical data associated with a patient in an electronic format.

## FHIR = Fast Healthcare Interoperability Resources

Fast Healthcare Interoperability Resources is a draft standard data format for resources that are part of health records and an Application Programming Interface (API) for exchanging those records.

## HAPI-FHIR = HL7 Application Programming Interface FHIR

Open source implementation of the HL7 FHIR specification for Java.

## HIE = Health Information Exchange

Health information exchanges (HIEs) facilitate the secure exchange of health information within and across states. Sharing information in this way is one of the requirements of meaningful use. The Office of the National Coordinator for Health Information Technology (ONC) has made 56 awards totally $548 million to help states and territories in the US develop secure health information exchanges. [Source: <https://www.healthit.gov/patients-families/faqs/what-health-information-exchange>]

## HIPAA = Health Insurance Portability and Accountability Act

The Health Insurance Portability and Accountability Act of 1996 is legislation that provides data security and privacy provisions for medical information.

## HISP = Health Information Service Provider

A Health Information Services Provider (HISP) is an organization that manages security and transport for health information exchange among health care entities or individuals using the Direct standard for transport. There is no specific legal designation for a HISP, nor are HISPs specifically regulated by Meaningful Use certification rules. The term HISP was coined to describe specific message transport functions that need to be performed to support scaled deployment of the Direct standard in the market. HISP functions can be performed by existing organizations (such as EHR vendors or hospitals or HIE organizations) or by standalone organizations specializing in HISP services. Source: <http://geekdoctor.blogspot.com/2014/03/a-primer-on-meaningful-use-and-hisps.html>

## HITECH = Health Information Technology for Economic and Clinical Health

HITECH (part of ARRA) funded HIE development efforts at the state level. It offered incentives to hospitals and health care providers for meaningful use of connected, certified electronic health records. It also offered funding for HIE development.

## HL7 = Health Level 7

Standards organization responsible for FHIR.

## ICD-10 = International Classification of Diseases 10th Edition

ICD-10 is a clinical cataloging system. Within the healthcare industry, providers, coders, IT professionals, insurance carriers, government agencies and others use ICD codes to properly note diseases on health records, track epidemiological trends, and assist in medical reimbursement decisions. Source: <http://searchhealthit.techtarget.com/definition/ICD-10>

## LOINC = Logical Observation Identifiers Names and Codes

See <http://loinc.org/>. LOINC consists of universal identifiers for laboratory and other clinical observations.

## Meaningful Use

Meaningful use is using certified electronic health record (EHR) technology to: Improve quality, safety, efficiency, and reduce health disparities. Engage patients and family. Improve care coordination, and population and public health. Maintain privacy and security of patient health information. Source: <https://www.healthit.gov/providers-professionals/meaningful-use-definition-objectives>

## MRN = Medical Record Number

The medical record number is organization specific. The number is used by the hospital as a systematic documentation of a patient´s medical history and care during each hospital stay. Source: <https://ushik.ahrq.gov/ViewItemDetails?system=ps&itemKey=88720000>

## PHI = Protected Health Information

Information in a medical record that identifies an individual created in the process of providing health care (e.g., a diagnosis or treatment).

## SHR = Standard Health Record

MITRE’s vision is to ***fundamentally shift*** how healthcare providers and individuals obtain and use pertinent information across multiple care domains to manage acute and preventive health. This shift begins with defining a Standard Health Record (SHR) to address the US healthcare system’s critical need for health data interoperability. The SHR vision is to enable unfettered multi-directional communication, driven by real-time, meaningful data, that empowers individuals and care teams to collaborate, reduce error and waste, and focus on the shared-decision making needed to build and maintain a healthy nation. Source: SHR Overview\_v3\_7\_25\_16.docx by Mary Quilty

## SNOMED = Systematized Nomenclature of Medicine

The Systematized Nomenclature of Medicine is a systematic, computer-processable collection of medical terms, in human and veterinary medicine, to provide codes, terms, synonyms and definitions which cover anatomy, diseases, findings, procedures, microorganisms, substances, etc. The standard is now more specifically called SNOMED-CT where CT stands for Clinical Terms. Source: <https://en.wikipedia.org/wiki/Systematized_Nomenclature_of_Medicine>

## STU = Standard for Trial Use

Current naming convention for releases of FHIR standard. STU3 is the latest release as of July 2016. Source: <http://hapifhir.io/>