第28回日本医療情報学会春季学術大会（シンポジウム2024）
テーマ「情報をつなぐ ～ゲノムから社会まで～」

チュートリアル１ 日本HL7協会「HL7 FHIR による接続事例のご紹介」

HL7 Vulcan FHIR Connectathon

医薬品規制領域における国際情報連携の取組み

2024年6月13日

日本HL7協会情報教育委員会/一般社団法人医療データ活用基盤整備機構
岡田美保子

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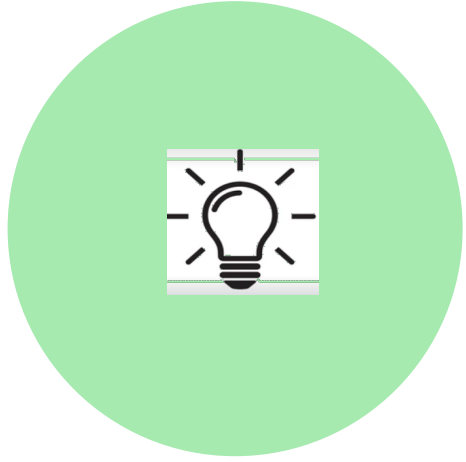
FHIRコネクタソン SPL・ePI・IDMP

グローバルな医薬品情報連携
国境を越えた服薬情報共有



HL7 FHIR

患者と医療者を繋ぐ

医薬品規制領域におけるFHIR

Vulcan, SPL, ePI, IDMP

医薬品規制領域におけるFHIR

HL7 FHIR Accelerator Program
HL7 Vulcan

臨床研究のための EHR データの取得・利用は日常ケアとは大きくかけ離れている

○医療ケアと臨床研究のギャップを埋める

○橋渡しと臨床研究のコミュニティを結ぶ

○臨床研究の設計・実施・報告の最適化

○そのための標準の開発・改良・使用

○世界の規制当局に包括的推奨事項を提供

必要な FHIR 研究リソースを成熟するまで開発

- Accelerator： HL7 FHIR加速化プログラム- Argnaut, The CARIN, CodeX, Da Vinci, FAST, Gravity, Helios, Vulcan
- Vulcan： 各テーマを行政、学界、IT企業、標準開発団体、患者、業界コンソーシアム等のファンドを受けた代表グループがリード

Vulcan project at a glance

Vulcan プロジェクト	概　　略	リーダー
Schedule of Activities (SoA)	既存の FHIR リソースを利用して、Spreadsheetからアクティビティのスケジュールを FHIRで表現する。試験におけるアクティビティの一貫性ある説明、タイミング、識別を可能にする	Mike Ward (TransCelerate) Geoff Low (PHUSE)
Real World Data (RWD)	臨床研究支援、規制当局への申請支援のため、Real World Dataソース (EHRシステム等) から研究データを標準化されたフォーマットでの取得に使用できる FHIR プロファイルを定義した FHIR IGを開発	Scott Gordon (FDA) Alex Cheng (Vanderbuilt)
Phenomics Exchange for Research and Diagnostics	表現型データを交換するための GA4GH（Global Alliance for Genomics and Health)の標準開発。ゲノム研究、ゲノム医療のため高品質の標準化された表現型情報の利用可能性を高める	Anita Valden (University of Colorado Anshutz) Shamih Essald (University of Colorado Anshutz)
Electronic Product Information (ePI)	患者のたの国境を越えたデータ交換を支えるため、医薬品の製品情報のための共通構造を定義する	Craig Anderson (Pfizer) Catherine Chronaki (Secretary General at HL7 Europe)
Adverse Events (AE)	有害事象の報告とフォーマットの標準化を支援する。関連するFHIRリソースの成熟度を改善する	Michelle Casagni (MITRE) Ed Millikan (FDA)
FHIR to OMOP	FHIR から OMOP 研究用の臨床データのより優れた分析のために、FHIR から OMOP へのデータ転送の開発をサポート	Davera Gabriel (Evidentli)
Sample Data	Vulcanのアプリケーションや実装ガイドのテストに用いるのに適切なデータセットを提供	Catharine Craven (Independent, SME) Rusell Leftwich (InterSystems)

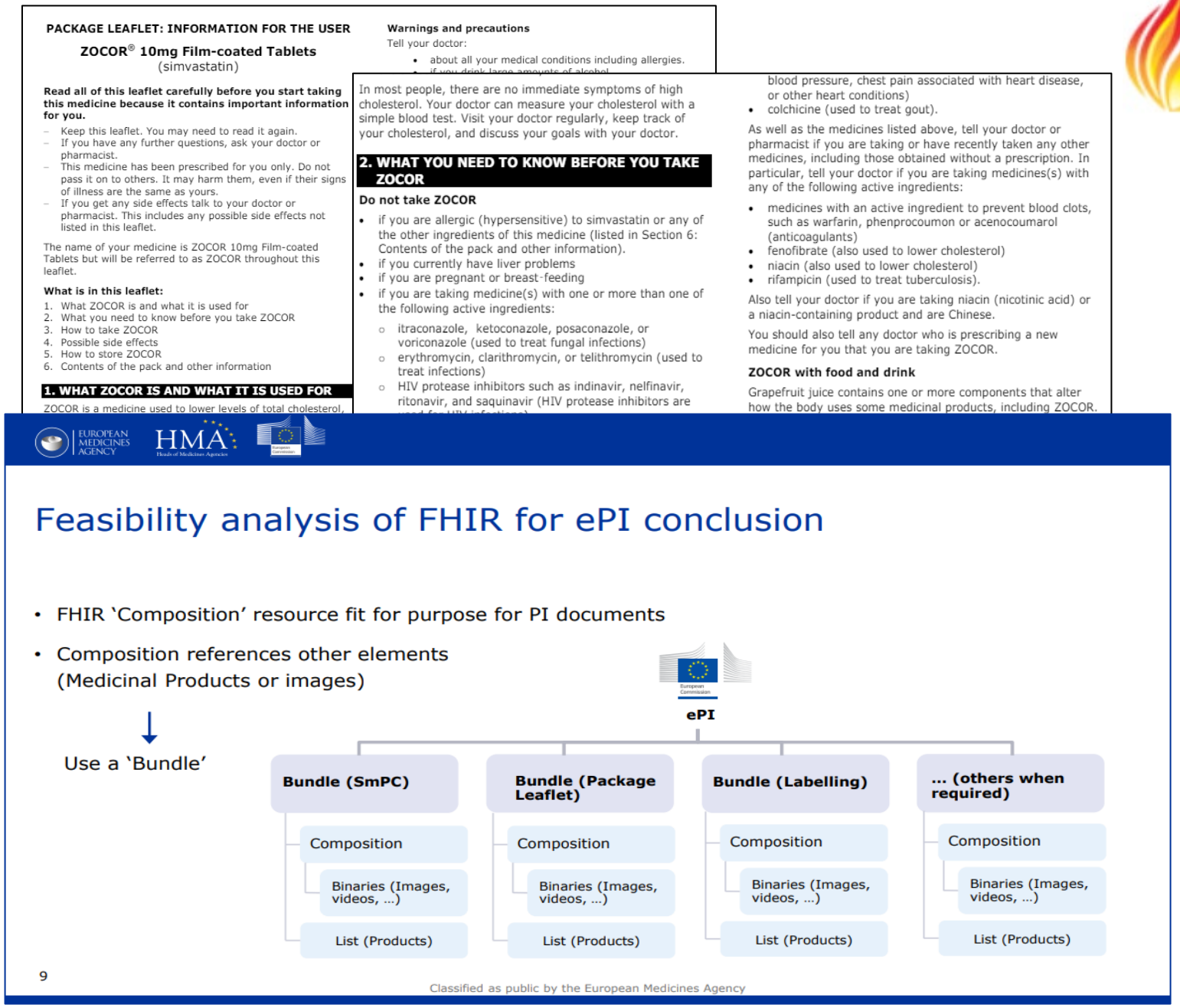
ePI – electronic Product Information

PI (Product Information)

- EUの医薬品製品情報
  - 患者向け添付文書
  - 医療者向け製品特性（SmPC）要約
  - ラベリング

ePI (electronic PI)

- FHIR EU ePI Common Standard (GitHubにinformal公開)
- 各種ユースケースへの対応
- 自動更新通知、サポートビデオ/オーディオコンテンツへのアクセス、オンライン副作用報告ツールなどの機能拡張計画



PACKAGE LEAFLET: INFORMATION FOR THE USER

ZOCOR® 10mg Film-coated Tablets
(simvastatin)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

The name of your medicine is ZOCOR 10mg Film-coated Tablets but will be referred to as ZOCOR throughout this leaflet.

What is in this leaflet:

1. What ZOCOR is and what it is used for
2. What you need to know before you take ZOCOR
3. How to take ZOCOR
4. Possible side effects
5. How to store ZOCOR
6. Contents of the pack and other information

1. WHAT ZOCOR IS AND WHAT IT IS USED FOR

ZOCOR is a medicine used to lower levels of total cholesterol,

Warnings and precautions

Tell your doctor:

- about all your medical conditions including allergies.

In most people, there are no immediate symptoms of high cholesterol. Your doctor can measure your cholesterol with a simple blood test. Visit your doctor regularly, keep track of your cholesterol, and discuss your goals with your doctor.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ZOCOR

Do not take ZOCOR

- if you are allergic (hypersensitive) to simvastatin or any of the other ingredients of this medicine (listed in Section 6: Contents of the pack and other information).
- if you currently have liver problems
- if you are pregnant or breast-feeding
- if you are taking medicine(s) with one or more than one of the following active ingredients:
  - itraconazole, ketoconazole, posaconazole, or voriconazole (used to treat fungal infections)
  - erythromycin, clarithromycin, or telithromycin (used to treat infections)
  - HIV protease inhibitors such as indinavir, nelfinavir, ritonavir, and saquinavir (HIV protease inhibitors are

blood pressure, chest pain associated with heart disease, or other heart conditions)

- colchicine (used to treat gout).

As well as the medicines listed above, tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription. In particular, tell your doctor if you are taking medicines(s) with any of the following active ingredients:

- medicines with an active ingredient to prevent blood clots, such as warfarin, phenprocoumon or acenocoumarol (anticoagulants)
- fenofibrate (also used to lower cholesterol)
- niacin (also used to lower cholesterol)
- rifampicin (used to treat tuberculosis).

Also tell your doctor if you are taking niacin (nicotinic acid) or a niacin-containing product and are Chinese.

You should also tell any doctor who is prescribing a new medicine for you that you are taking ZOCOR.

ZOCOR with food and drink

Grapefruit juice contains one or more components that alter how the body uses some medicinal products, including ZOCOR.

EUROPEAN MEDICINES AGENCY HMA

Feasibility analysis of FHIR for ePI conclusion

- FHIR 'Composition' resource fit for purpose for PI documents
- Composition references other elements (Medicinal Products or images)

Use a 'Bundle'

ePI

Bundle (SmPC)	Bundle (Package Leaflet)	Bundle (Labelling)	... (others when required)
Composition	Composition	Composition	Composition
Binaries (Images, videos, ...)	Binaries (Images, videos, ...)	Binaries (Images, videos, ...)	Binaries (Images, videos, ...)
List (Products)	List (Products)	List (Products)	List (Products)

9

Classified as public by the European Medicines Agency

https://www.ema.europa.eu/en/documents/presentation/presentation-fhir-eu-common-standard-epi-g-rodriguez_en.pdf

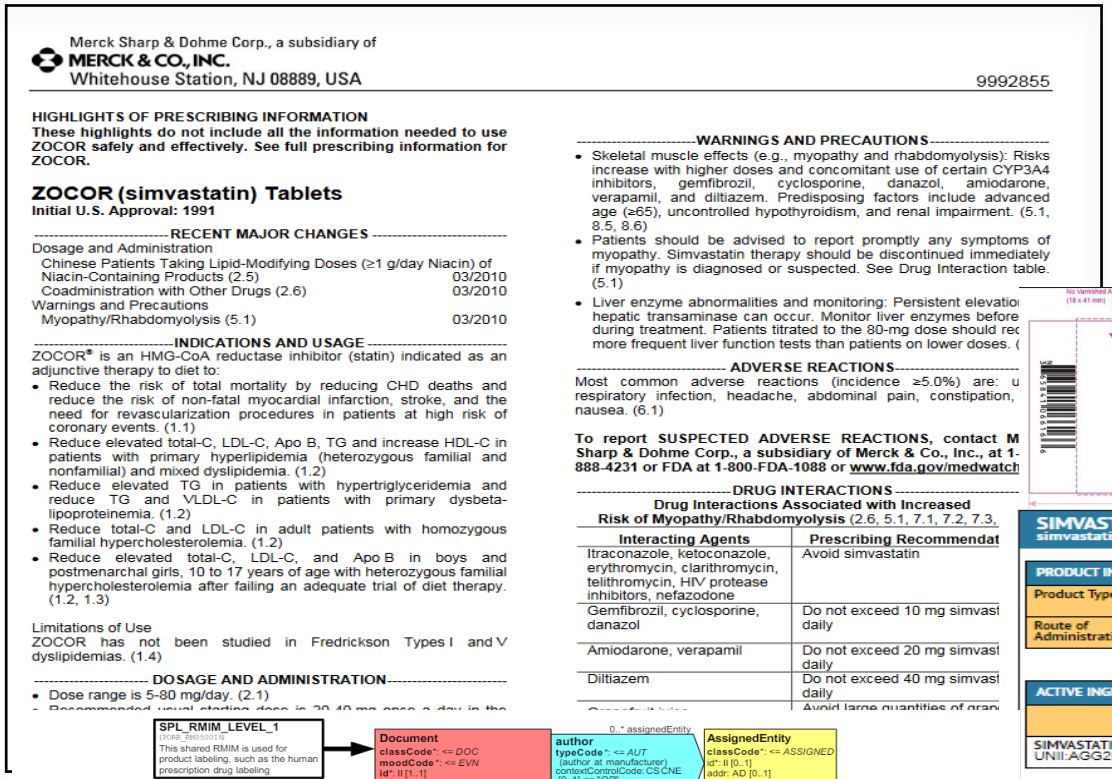
FDA SPL (Structured Package Labeling)

○医薬品ラベル(Lable)は日本の添付文書の内容に近いドキュメント

○SPL(Structured Package Labeling)はその伝送規格

- 処方薬と市販薬 (OTC) の両方の構造化された製品ラベル
- HL7 V3で開発された規格

○HL7 V3 SPLモデル開発、交換メッセージ、多数のドキュメンテーション



Merck Sharp & Dohme Corp., a subsidiary of
MERCK & CO., INC.
Whitehouse Station, NJ 08889, USA

9992855

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use ZOCOR safely and effectively. See full prescribing information for ZOCOR.

ZOCOR (simvastatin) Tablets
Initial U.S. Approval: 1991

RECENT MAJOR CHANGES

Dosage and Administration
Chinese Patients Taking Lipid-Modifying Doses (≥1 g/day Niacin) of Niacin-Containing Products (2.5) 03/2010
Coadministration with Other Drugs (2.6) 03/2010
Warnings and Precautions
Myopathy/Rhabdomyolysis (5.1) 03/2010

INDICATIONS AND USAGE

ZOCOR® is an HMG-CoA reductase inhibitor (statin) indicated as an adjunctive therapy to diet to:

- Reduce the risk of total mortality by reducing CHD deaths and reduce the risk of non-fatal myocardial infarction, stroke, and the need for revascularization procedures in patients at high risk of coronary events. (1.1)
- Reduce elevated total-C, LDL-C, Apo B, TG and increase HDL-C in patients with primary hyperlipidemia (heterozygous familial and nonfamilial) and mixed dyslipidemia. (1.2)
- Reduce elevated TG in patients with hypertriglyceridemia and reduce TG and VLDL-C in patients with primary dysbeta-lipoproteinemia. (1.2)
- Reduce total-C and LDL-C in adult patients with homozygous familial hypercholesterolemia. (1.2)
- Reduce elevated total-C, LDL-C, and Apo B in boys and postmenarchal girls, 10 to 17 years of age with heterozygous familial hypercholesterolemia after failing an adequate trial of diet therapy. (1.2, 1.3)

Limitations of Use
ZOCOR has not been studied in Fredrickson Types I and V dyslipidemias. (1.4)

DOSAGE AND ADMINISTRATION

- Dose range is 5-80 mg/day. (2.1)

WARNINGS AND PRECAUTIONS

- Skeletal muscle effects (e.g., myopathy and rhabdomyolysis): Risks increase with higher doses and concomitant use of certain CYP3A4 inhibitors, gemfibrozil, cyclosporine, danazol, amiodarone, verapamil, and diltiazem. Predisposing factors include advanced age (≥65), uncontrolled hypothyroidism, and renal impairment. (5.1, 8.5, 8.6)
- Patients should be advised to report promptly any symptoms of myopathy. Simvastatin therapy should be discontinued immediately if myopathy is diagnosed or suspected. See Drug Interaction table. (5.1)
- Liver enzyme abnormalities and monitoring: Persistent elevatio hepatic transaminase can occur. Monitor liver enzymes before during treatment. Patients titrated to the 80-mg dose should rec more frequent liver function tests than patients on lower doses. (

ADVERSE REACTIONS

Most common adverse reactions (incidence ≥5.0%) are: u respiratory infection, headache, abdominal pain, constipation, nausea. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact M Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., at 1-888-4231 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

DRUG INTERACTIONS

Drug Interactions Associated with Increased Risk of Myopathy/Rhabdomyolysis (2.6, 5.1, 7.1, 7.2, 7.3,

Interacting Agents	Prescribing Recommendat
Itraconazole, ketoconazole, erythromycin, clarithromycin, telithromycin, HIV protease inhibitors, nefazodone	Avoid simvastatin
Gemfibrozil, cyclosporine, danazol	Do not exceed 10 mg simvast daily
Amiodarone, verapamil	Do not exceed 20 mg simvast daily
Diltiazem	Do not exceed 40 mg simvast daily

SIMVASTATIN
simvastatin tablet, film coated

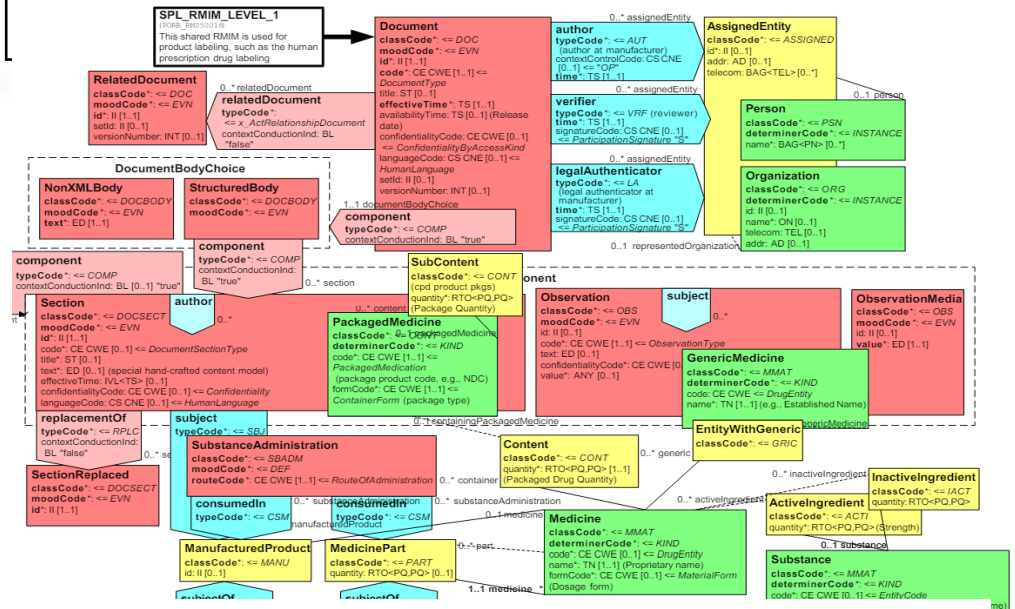
PRODUCT INFORMATION			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-066
Route of Administration	ORAL		

ACTIVE INGREDIENT/ACTIVE MOIETY		
Ingredient Name	Basis of Strength	Strength
SIMVASTATIN (UNII: AGG2FN16EV) (SIMVASTATIN - UNII:AGG2FN16EV)	SIMVASTATIN	10 mg

INACTIVE INGREDIENTS	
Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

PRODUCT CHARACTERISTICS			
Color	PINK (PINK)	Score	no score
Shape	OVAL (OVAL)	Size	9mm
Flavor		Imprint Code	ZA20
Contains			

PACKAGING				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-066-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2006	
2	NDC:65841-066-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2006	
3	NDC:65841-	90 in 1 BOTTLE; Type 0:	12/20/2006	



From HL7 Structured Product Labeling 2 Release 2 3 Committee Ballot – December 2004

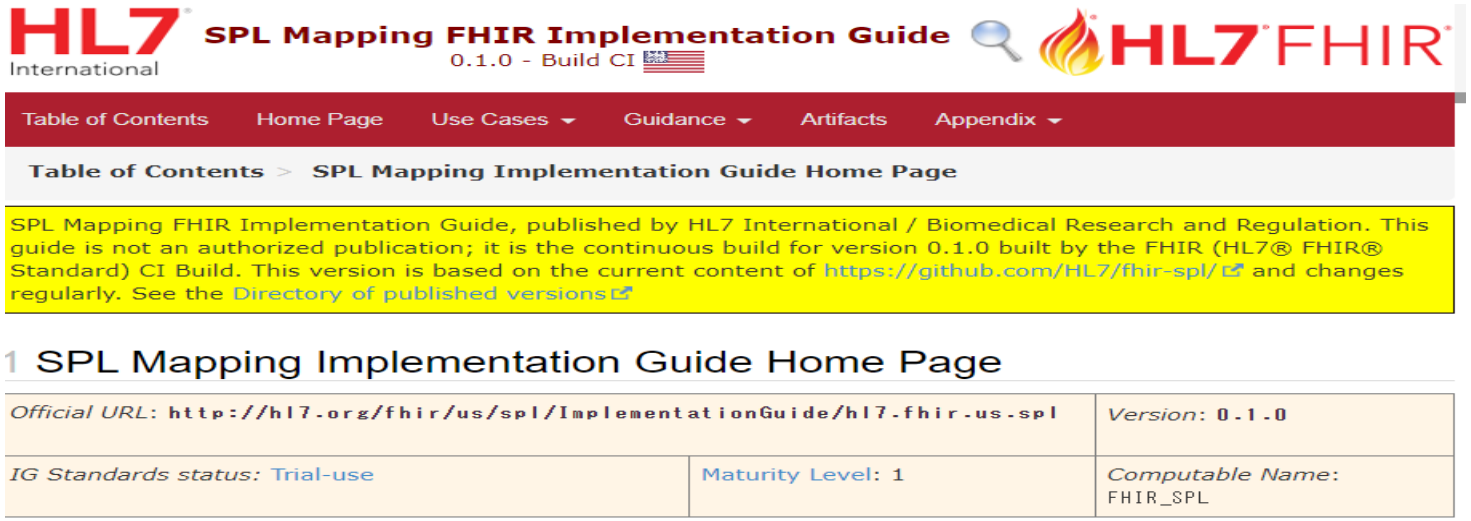
FDA SPL (Structured Package Labeling)

○医薬品ラベル(Lable)は日本の添付文書の内容に近いドキュメント

○SPL(Structured Package Labeling)はその伝送規格

- 処方薬と市販薬 (OTC) の両方の構造化された製品ラベル
- HL7 V3で開発

- HL7 V3 SPLからFHIRへの移行
- SPL HL7 V3とFHIRのマッピング
- HL7 V3 SPLとFHIRの両方を受信できるdual submission architecture



SPL Use Cases

The first phase of the project focuses on SPL-to-FHIR and FHIR-to-SPL data element mapping and processing related to Medicinal Products and Establishment/Facility Registration. The scope includes the four use cases listed below along with their corresponding SPL document types:

1.UC01 - Request an NDC Labeler Code
   1. 51726-8 NDC Labeler Code Request
   2. 69968-6 NDC Labeler Code Inactivation

2.UC02 - Register or updated the information of an Establishment
   1. 51725-0 Establishment Registration
   2. 70097-1 Establishment De-Registration
   3. 53410-7 No Change Notification
   4. 53411-5 Out of Business Notification

3.UC03 - Submit GDUFA Facility Self-Identification
   1. 71743-9 Generic Drug Facility Identification Submission
   2. 72090-4 Identification of CBER-regulated generic drug facility

4.UC04 - Submit a Drug or Biologic Label
   1. 53409-9 Bulk Ingredient
   2. 60684-8 Cellular Therapy
   3. 78744-0 Drug for Further Processing
   4. 75031-5 Human Compounded Drug Label
   5. 34390-5 Human OTC Drug Label
   6. 34391-3 Human Prescription Drug Label
   7. 53408-1 Licensed Minimally Manipulated Cells Label
   8. 53406-5 Licensed Vaccine Bulk Intermediate Label
   9. 53405-7 Non-Standardized Allergenic Label
   10. 60683-0 Plasma Derivative
   11. 60682-2 Standardized Allergenic
   12. 53404-0 Vaccine Label
   13. 86445-4 Blanket No Changes Certification of Product Listing

At the end of this phase, this guide will have captured the following:

- SPL-to-FHIR and FHIR-to-SPL data elements mappings for the SPL document types listed above
- FHIR profiles that correspond to the SPL document types listed above
- XSL Transforms that convert from SPL to FHIR and from FHIR to SPL

IDMP (Identification of Medicinal Products)

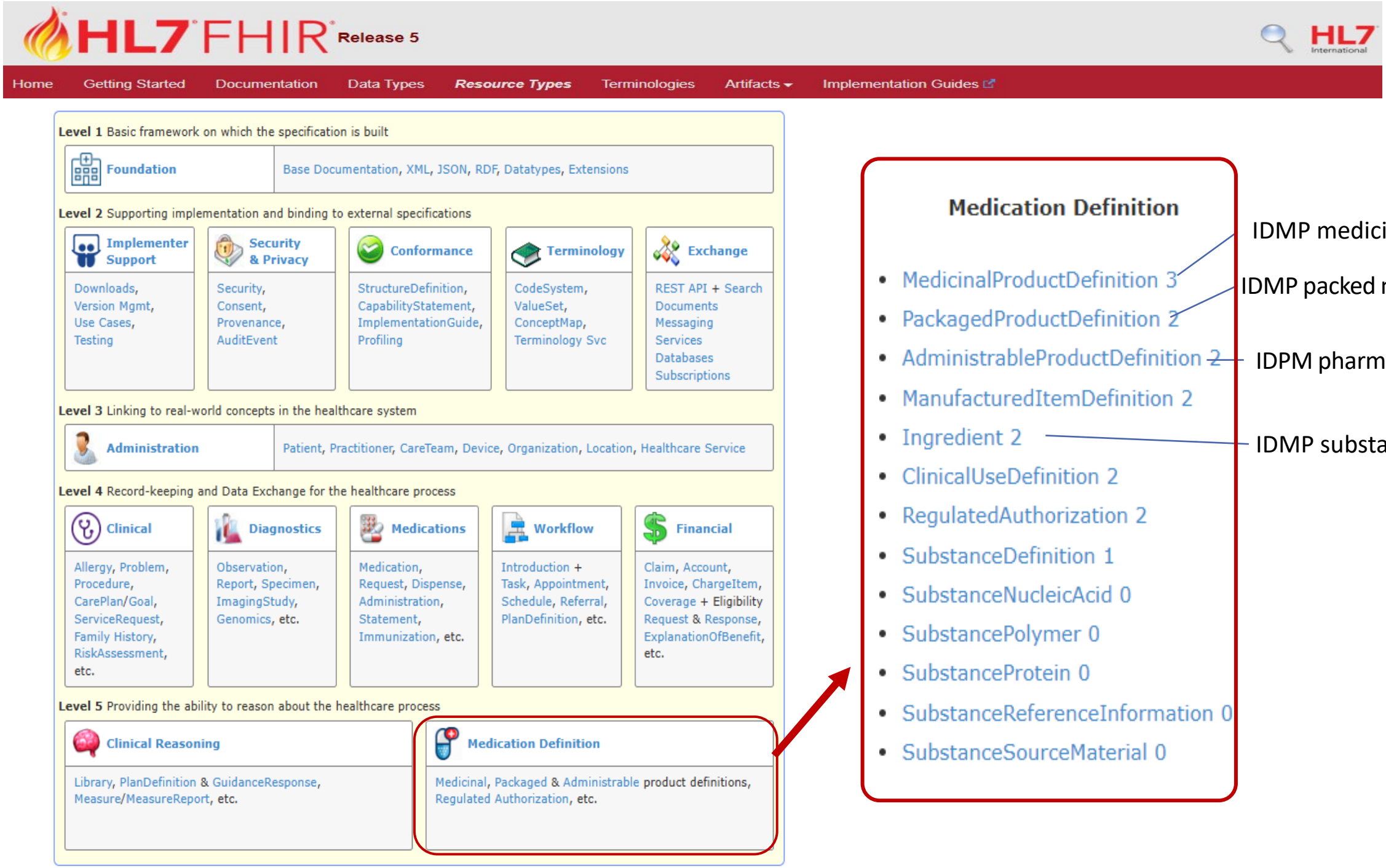
○ 医薬品識別に係る国際規格
○ 5つのISO規格からなる
○ 欧州中心に普及を推進

○ HL7 FHIRの開発
- 医薬品規制領域に係るFHIRリソース開発
- FDA、EMA等規制当局からも参画
- 規制領域のプロジェクトで活用

by Christhian Hay氏スライドより

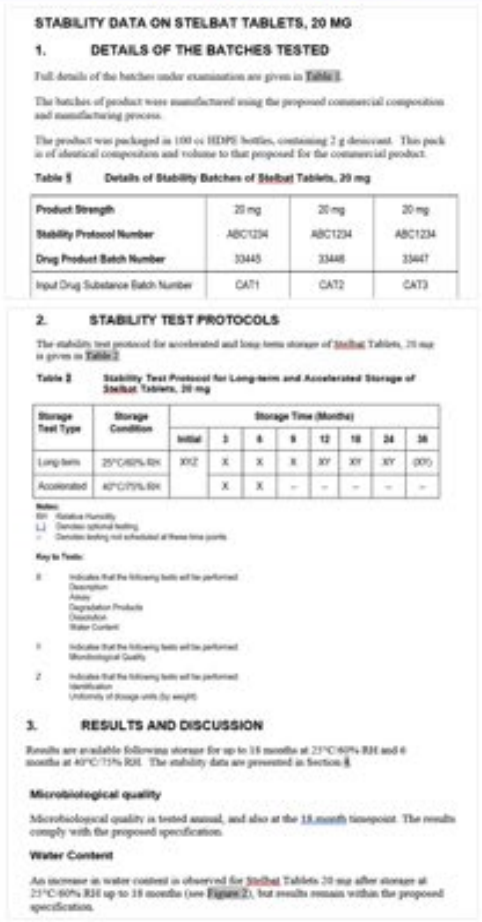
UNICOMプロジェクト：
EUのファンド(2024年5月末まで)を得て活動
規制、臨床プロセスでのIDMP導入に焦点

ISO IDMP (Identification of Medicinal Products)		
ISO 11615	MPID (Medicinal Product Identification)	商品名に対するID
ISO 11616	PhPID (Pharmaceutical Product Identifier)	製剤に対するID
ISO 11238	SubID (Substance Identification)	成分名に対するID
ISO 11239	Dosage Form and Route of Administration	剤型・投与経路・表現単位・パッケージ
ISO 11240	Units of Measurement (UoM)	用量単位


HL7 FHIR Release 5
HL7 International
Home
Getting Started
Documentation
Data Types
Resource Types
Terminologies
Artifacts
Implementation Guides
Level 1 Basic framework on which the specification is built
Foundation
Base Documentation, XML, JSON, RDF, Datatypes, Extensions
Level 2 Supporting implementation and binding to external specifications
Implementer Support
Downloads, Version Mgmt, Use Cases, Testing
Security & Privacy
Security, Consent, Provenance, AuditEvent
Conformance
StructureDefinition, CapabilityStatement, ImplementationGuide, Profiling
Terminology
CodeSystem, ValueSet, ConceptMap, Terminology Svc
Exchange
REST API + Search
Documents
Messaging
Services
Databases
Subscriptions
Level 3 Linking to real-world concepts in the healthcare system
Administration
Patient, Practitioner, CareTeam, Device, Organization, Location, Healthcare Service
Level 4 Record-keeping and Data Exchange for the healthcare process
Clinical
Allergy, Problem, Procedure, CarePlan/Goal, ServiceRequest, Family History, RiskAssessment, etc.
Diagnostics
Observation, Report, Specimen, ImagingStudy, Genomics, etc.
Medications
Medication, Request, Dispense, Administration, Statement, Immunization, etc.
Workflow
Introduction + Task, Appointment, Schedule, Referral, PlanDefinition, etc.
Financial
Claim, Account, Invoice, ChargeItem, Coverage + Eligibility Request & Response, ExplanationOfBenefit, etc.
Level 5 Providing the ability to reason about the healthcare process
Clinical Reasoning
Library, PlanDefinition & GuidanceResponse, Measure/MeasureReport, etc.
Medication Definition
Medicinal, Packaged & Administrable product definitions, Regulated Authorization, etc.
Medication Definition
MedicinalProductDefinition 3
PackagedProductDefinition 2
AdministrableProductDefinition 2
ManufacturedItemDefinition 2
Ingredient 2
ClinicalUseDefinition 2
RegulatedAuthorization 2
SubstanceDefinition 1
SubstanceNucleicAcid 0
SubstancePolymer 0
SubstanceProtein 0
SubstanceReferenceInformation 0
SubstanceSourceMaterial 0
IDMP medicinal product
IDMP packed medicinal product
IDPM pharmaceutical product
IDMP substance

Legacy format からFHIRへ- FHIR IG Pharmaceutical Quality (Industry)の例

Legacy Format → **FHIR Implementation Guide** → **FHIR Representation**



STABILITY DATA ON STELBAT TABLETS, 20 MG

1. DETAILS OF THE BATCHES TESTED

Full details of the batches under examination are given in Table 1.

The batches of product were manufactured using the proposed commercial composition and manufacturing process.

The product was packaged in 100 cc HDPE bottles, containing 2 g desiccant. This pack is of identical composition and volume to that proposed for the commercial product.

Table 1 Details of Stability Batches of Stelbat Tablets, 20 mg

Product Strength	20 mg	20 mg	20 mg
Stability Protocol Number	ABC1234	ABC1234	ABC1234
Drug Product Batch Number	33445	33446	33447
Input Drug Substance Batch Number	CAT1	CAT2	CAT3

2. STABILITY TEST PROTOCOLS

The stability test protocol for accelerated and long-term storage of Stelbat Tablets, 20 mg is given in Table 2.

Table 2 Stability Test Protocol for Long-term and Accelerated Storage of Stelbat Tablets, 20 mg

Storage Test Type	Storage Condition	Storage Time (Months)							
		Initial	3	6	9	12	18	24	36
Long-term	25°C/60% RH	X(2)	X	X	X	X(Y)	X(Y)	X(Y)	(X(Y))
Accelerated	40°C/75% RH		X	X	--	--	--	--	--

Notes:
RH Relative Humidity
( ) Denotes optional testing
-- Denotes testing not scheduled at these time points

Key to Tests:

X Indicates that the following tests will be performed:
Description
Assay
Degradation Products
Dissolution
Water Content

Y Indicates that the following tests will be performed:
Microbiological Quality

Z Indicates that the following tests will be performed:
Identification
Uniformity of dosage units (by weight)

3. RESULTS AND DISCUSSION

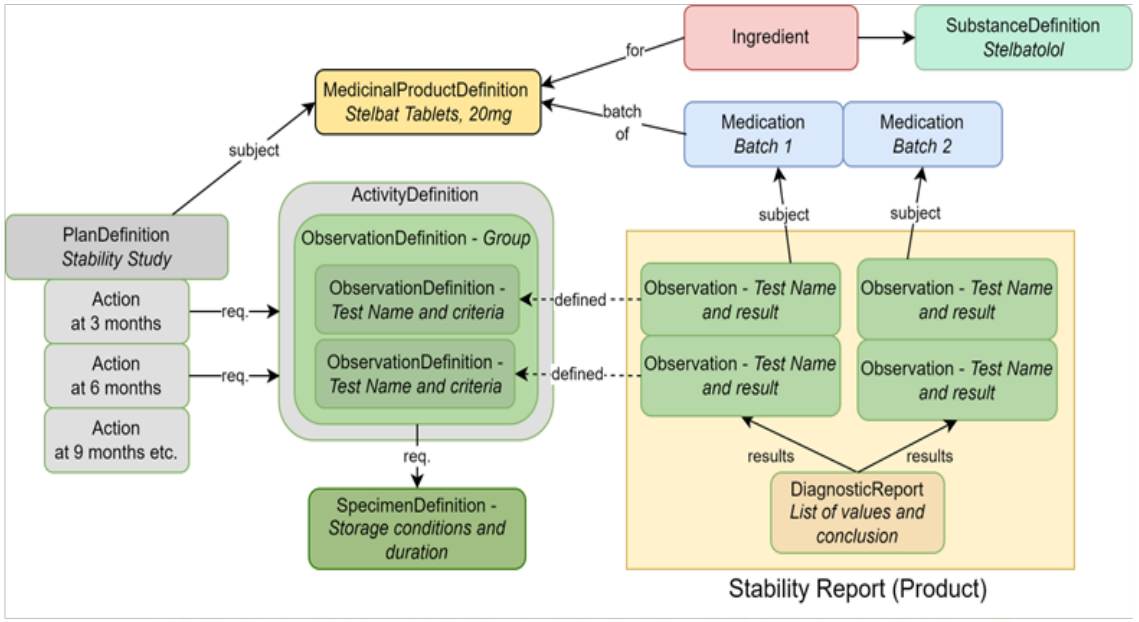
Results are available following storage for up to 18 months at 25°C/60% RH and 6 months at 40°C/75% RH. The stability data are presented in Section 8.

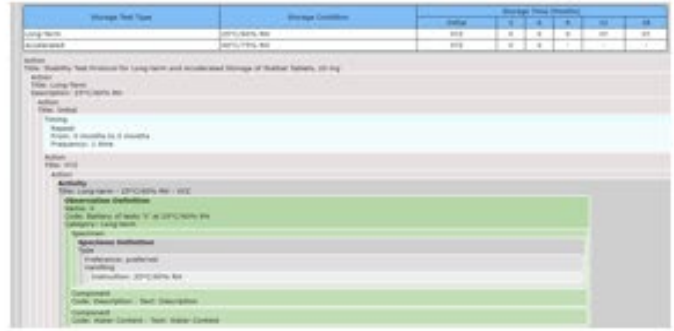
Microbiological quality

Microbiological quality is tested annual, and also at the 18 month timepoint. The results comply with the proposed specification.

Water Content

An increase in water content is observed for Stelbat Tablets 20 mg after storage at 25°C/60% RH up to 18 months (see Figure 2), but results remain within the proposed specification.





[Home Page – FHIR IG Pharmaceutical Quality (Industry)]

CMC: Chemistry, Manufacturing and Control

Pfizer Research and Development – Global Regulatory Sciences

著者の許諾を得て転載: Craig Anderson, Pfizer. Vulcan - April Implementation Showcase, April 2024より

HL7 Vulcan FHIR Connectathon

医薬品規制領域における国際情報連携の取組み

情報をつなぐ - 患者と医療者をつなぐ

- 実践的な FHIR 開発とテストを特徴とする
- 実装者、開発者はFHIR 仕様を推進する技術的議論を行い、FHIRベースのソリューションを開発し、他FHIRインターフェイスとデータを実際に交換するために集まる
- FHIR 開発者、標準開発チームのリーダ層と直接連携できる

September 2023　FHIR Connectathon
Tack: Vulcan/Gravitate Health - ePI/IPS and SPL-FHIR

Track Objective

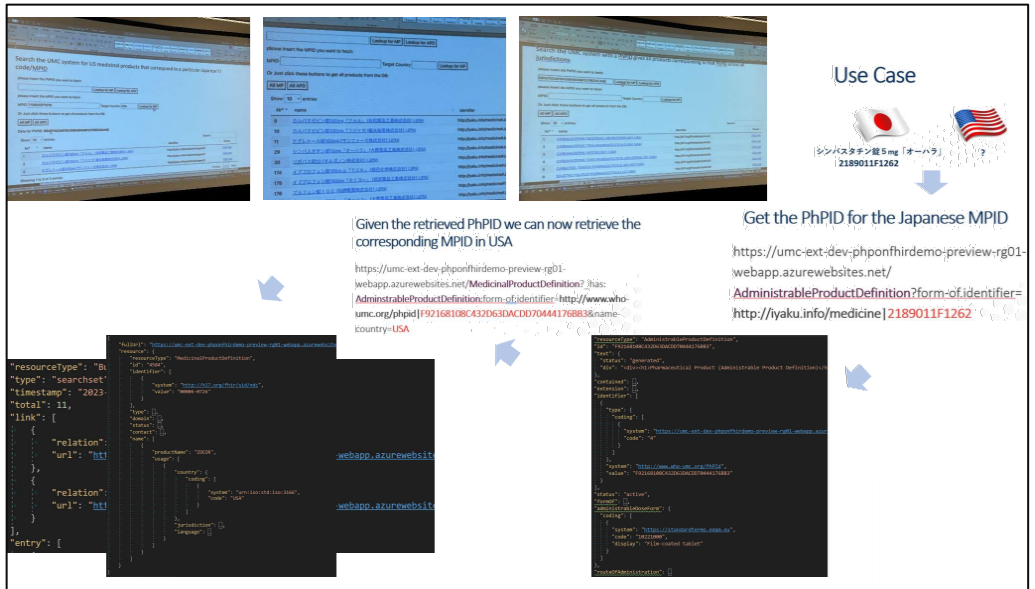
- **シナリオ #1:** ePI を SPL-FHIR に手動で変換して Vulcan ePI と SPL-FHIR 間の接続を確立する
- **シナリオ #2:** 患者は米国から欧州に旅行、米国の処方箋に似た欧州の医薬品を見つける必要がある
- **シナリオ #3:** 患者は日本から米国に旅行し、日本の処方箋に似た米国の医薬品を見つける必要がある
- **シナリオ #4:** IDMP 識別子を ePI に組み込み国際接続を容易にする。PhPID の生成に焦点を当てる。旅行者のテスト シナリオをサポートするため、国境を越えて医薬品識別子を照合する

旅行者が持参している医薬品のMPIDをPhPIDメンテナンス機関へ送信

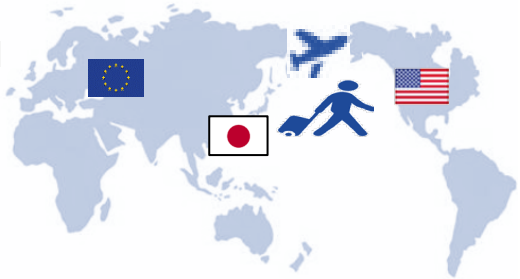
PhPID メンテナンス機関からマッチする訪問国のMPIDリストを取得

PhPIDメンテナンス機関

- WHO UMCで開発中
- Connectathonではテスト用DBを利用



HL7 FHIR CONNECTATHON



シナリオ #3: 日本から米国に旅行し、米国滞在中に服用している薬を切らして類似の薬を見つけたい

Travel from Japan to USA

Tanaka embarks on an international journey from Japan to the United States, poised for his anticipated vacation.

Forgotten Medication

Tanaka inadvertently forgets to carry an adequate medication supply for his three-week vacation in the United States.

Challenge: Dispensing a foreign prescription in the US

There are only few pharmacies in the US that can dispense a foreign prescription.

The pharmacist in US cannot type the Japanese brand name in his own software system.

This provokes genuine concern over potential prescription misinterpretation and erroneous medication dispensation.

Japanese ePrescription

Luckily, Tanaka can leverage a healthcare mobile app to access an electronic prescription for his medication, which he can presents to a U.S. pharmacist.

If we had a global PhPID

Global PhPID level 4 is luckily available in the Japanese prescription.

Tanaka now holds out the prescription confidently, a bridge between languages and cultures.

Therapy compliance is successfully ensured preserving patient's health.

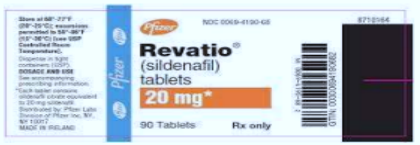
コネクタソン　テストシナリオ#3

The value of PhPID in cross border healthcare

Global IDMP Working Group

sildenafil 20mg tablets

sildenafil 20mg tablets



Global Phpid lvl 4

D934E701B1FF6B452828E1C6703B257E

Global PhPID level 4 is luckily available in the Japanese prescription.

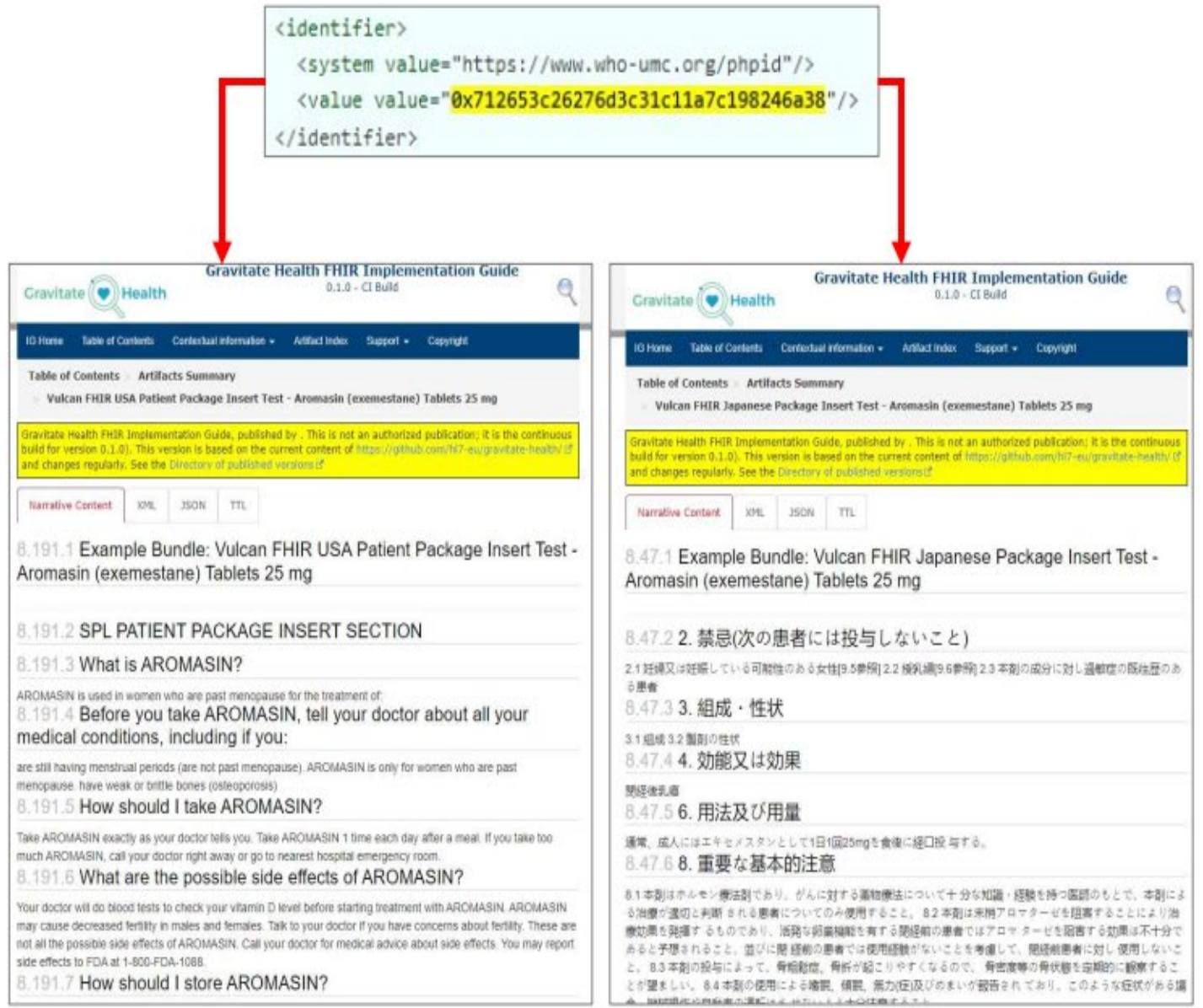
This allows the American pharmacist to search in his own system for medicinal products US FDA approved in the US market that share the same PhPID level 4. Language is no longer a barrier.

日本のMPIDは未定義 → 服用している薬のMPIDからPhpIDを調べる
相当する米国のMPIDを得る

Use case example 2: IDMP's Pharmaceutical Product Identifier (PhPID)

- US and Japanese Package Insert:
  - Two different labels.
  - Two different languages.
  - Same product: exemestane 25 mg tablets.
  - Same PhPID different formulations.

- Allows for an international search of all label documents with this PhPID.



Example API calls for cross border MPID lookup

https://confluence.hl7.org/download/attachments/175610822/Example%20API%20calls%20for%20cross%20brder%20MPID%20lookup.pptx?version=3&modificationDate=1694479941252&api=v2

View a Japanese product given an ID

https://umc-ext-dev-phponfhirdemo-preview-rg01-webapp.azurewebsites.net/MedicinalProductDefinition?**identifier=http://iyaku.info/medicine|2189011F1262**


```
{
  "fullUrl": "https://umc-ext-dev-phponfhirdemo-preview-rg01-webapp.azurewebsites.net/
  "resource": {
    "resourceType": "MedicinalProductDefinition",
    "id": "Japan32",
    "identifier": [
      {
        "system": "http://iyaku.info/medicine",
        "value": "2189011F1262"
      }
    ],
    "type": …,
    "domain": …,
    "status": …,
    "contact": …,
    "name": [
      {
        "productName": "シンバスタチン錠５mg「オーハラ」",
        "usage": [
          {
            "country": {
              "coding": [
                {
                  "system": "urn:iso:std:iso:3166",
                  "code": "JPN"
                }
              ]
            },
            "jurisdiction": …,
            "language": …
          }
        ]
      }
    ]
  }
}
```

Get the PhPID for the Japanese MPID

https://umc-ext-dev-phponfhirdemo-preview-rg01-webapp.azurewebsites.net

/**AdministrableProductDefinition**?form-of.identifier=**http://iyaku.info/medicine|2189011F1262**


```
"resourceType": "AdministrableProductDefinition",
"id": "F92168108C432D63DACDD70444176BB3",
"text": {
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  "div": "<div><h1>Pharmaceutical Product (Administrable Product Definition)</h
},
"contained": [...],
"extension": [...],
"identifier": [
  {
    "type": {
      "coding": [
        {
          "system": "https://umc-ext-dev-phponfhirdemo-preview-rg01-webapp.azur
          "code": "4"
        }
      ]
    },
    "system": "http://www.who-umc.org/PhPId",
    "value": "F92168108C432D63DACDD70444176BB3"
  }
],
"status": "active",
"formOf": [...],
"administrableDoseForm": {
  "coding": [
    {
      "system": "https://standardterms.edqm.eu",
      "code": "10221000",
      "display": "Film-coated tablet"
    }
  ]
},
"routeOfAdministration": [...
```

Given the retrieved PhPID, retrieve the corresponding MPID in USA

https://umc-ext-dev-phponfhirdemo-preview-rg01-webapp.azurewebsites.net/**MedicinalProductDefinition**?_has:**AdminstrableProductDefinition**:form-of:identifier=**http://www.who-umc.org/phpid|F92168108C432D63DACDD70444176BB3**
&name-country=**USA**


```
"resourceType": "Bundle",
"type": "searchset",
"timestamp": "2023-09-10T21:05:34.2683601+00:00",
"total": 11,
"link": [
    {
        "relation": "self",
        "url": "https://umc-ext-dev-phponfhirdemo-preview-rg01-webapp.azurewebsite
    },
    {
        "relation": "next",
        "url": "https://umc-ext-dev-phponfhirdemo-preview-rg01-webapp.azurewebsite
    }
],
"entry": [
```



```
{
    "fullUrl": "https://umc-ext-dev-phponfhirdemo-preview-rg01-webapp.azurewebsite
    "resource": {
        "resourceType": "MedicinalProductDefinition",
        "id": "4584",
        "identifier": [
            {
                "system": "http://hl7.org/fhir/sid/ndc",
                "value": "00006-0726"
            }
        ],
        "type": …,
        "domain": …,
        "status": …,
        "contact": …,
        "name": [
            {
                "productName": "ZOCOR",
                "usage": [
                    {
                        "country": {
                            "coding": [
                                {
                                    "system": "urn:iso:std:iso:3166",
                                    "code": "USA"
                                }
                            ]
                        },
                        "jurisdiction": …,
                        "language": …
                    }
                ]
            }
        ]
    }
}
```

HL7 FHIR

情報をつなぐ - 患者と医療者をつなぐ

ご清聴ありがとうございました