



Domestic status of eCTD and electronic submissions for clinical trials

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2024.11.13.



Pharmaceutical Policy Division, Pharmaceutical Safety Bureau
Ministry of Food and Drug Safety

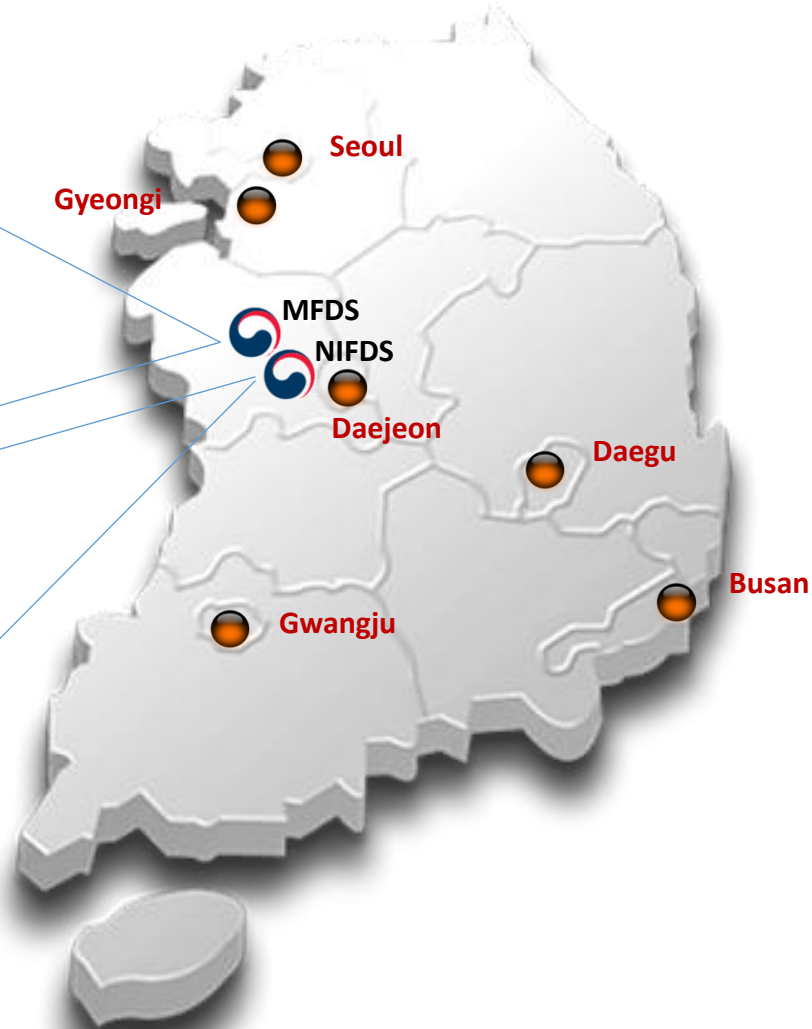
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- 2. NDA/BLA Approval Process & Data Submission**
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- 4. Efforts to Domestic Implementation for CDISC standard**
- 5. Submit an eCTD and CDISC to the MFDS**
- 6. CDISC Status in Domestic Pharmaceutical Industry**
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Status of CDISC in Korea


1. Introduction of MFDS

Introduction of MFDS



 Ministry of Food and Drug Safety

 MINISTRY OF FOOD AND DRUG SAFETY
National Institute of Food and Drug Safety Evaluation

 6 Regional Office of Food and Drug Safety

Member of ICH (2016~)
WHO Listed Authorities(2023~)

Our Vision, Core Strategies

Vision

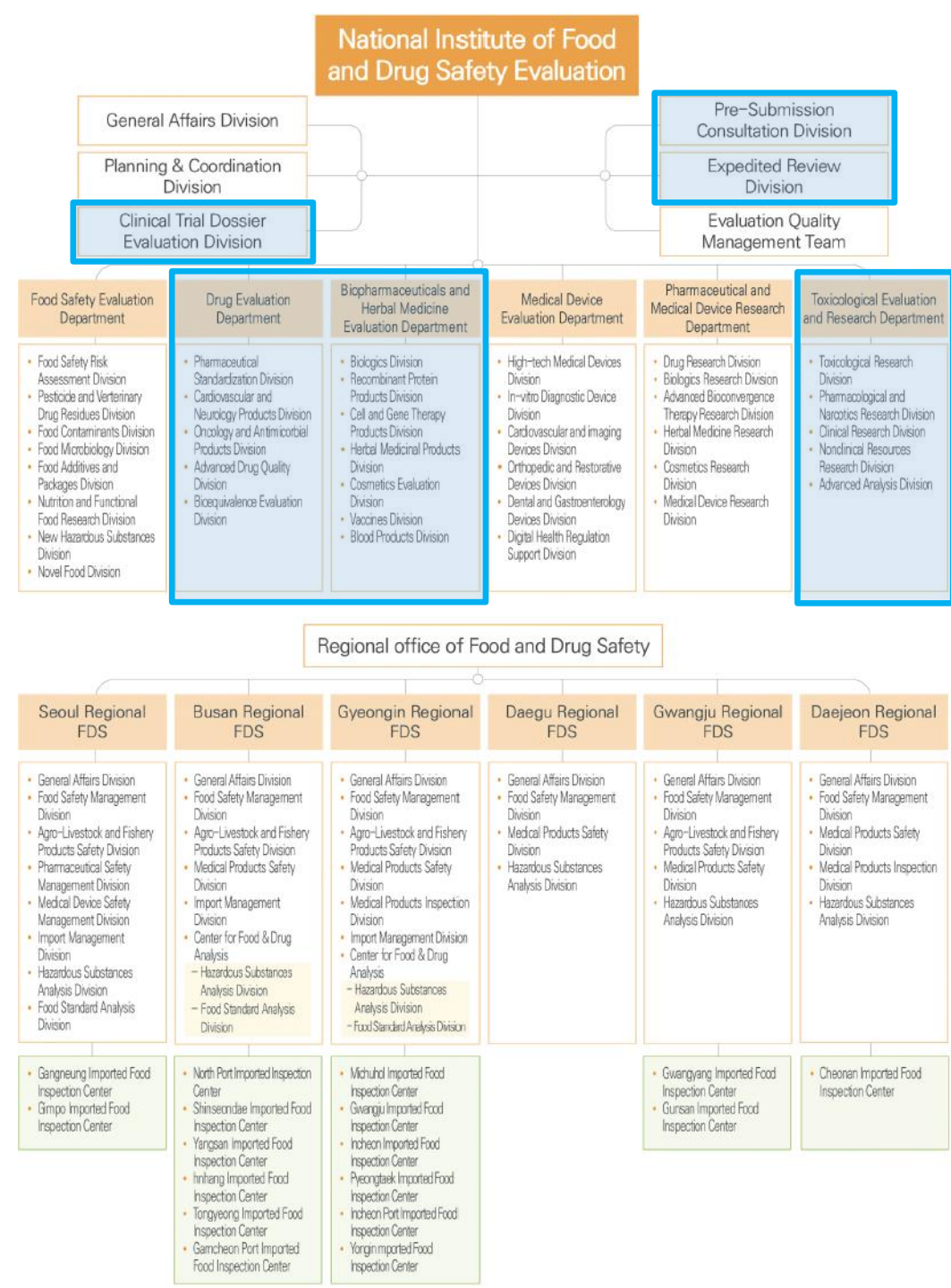
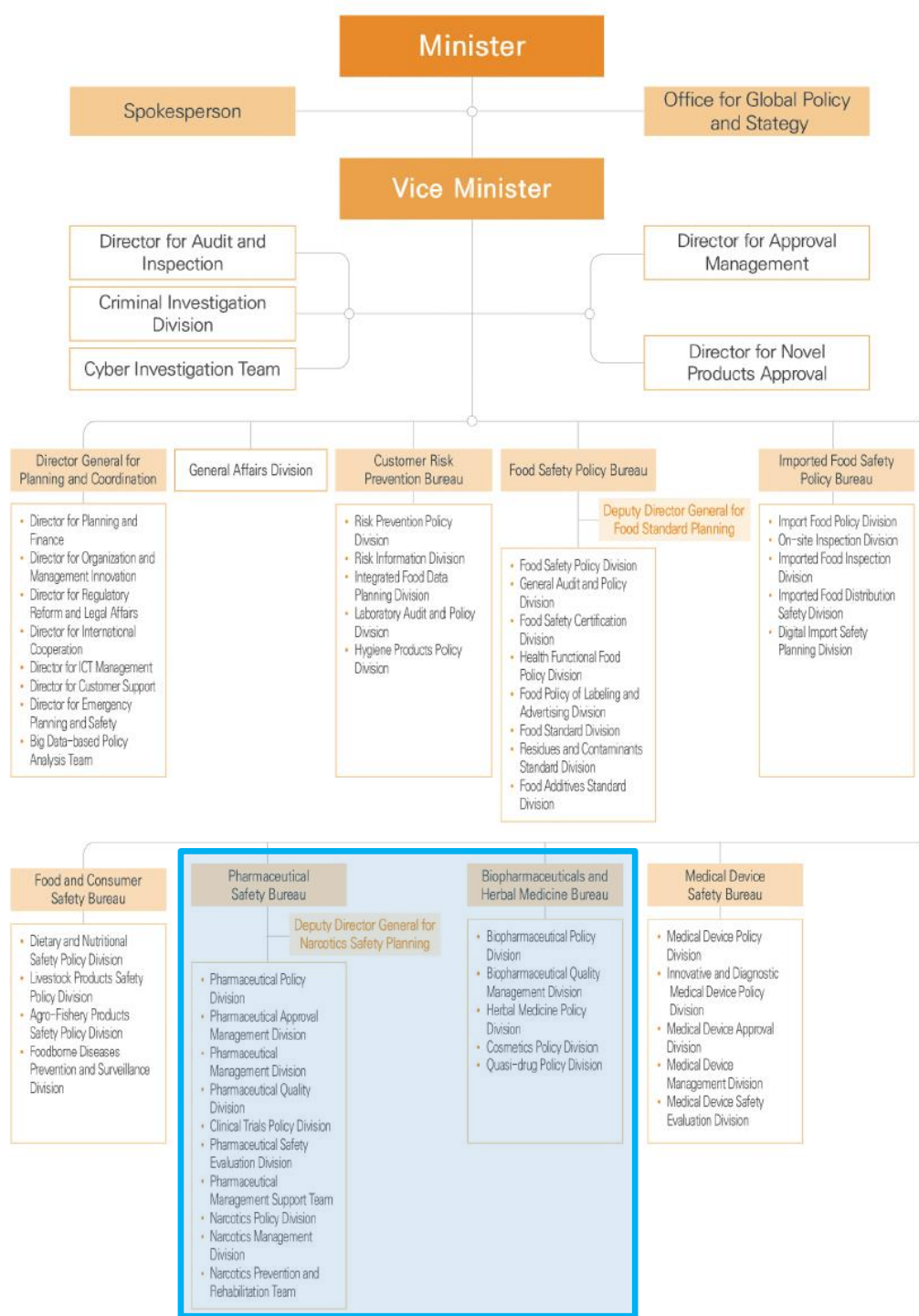
Core Value



A world where food and drug
safety are a **routine**



Organization

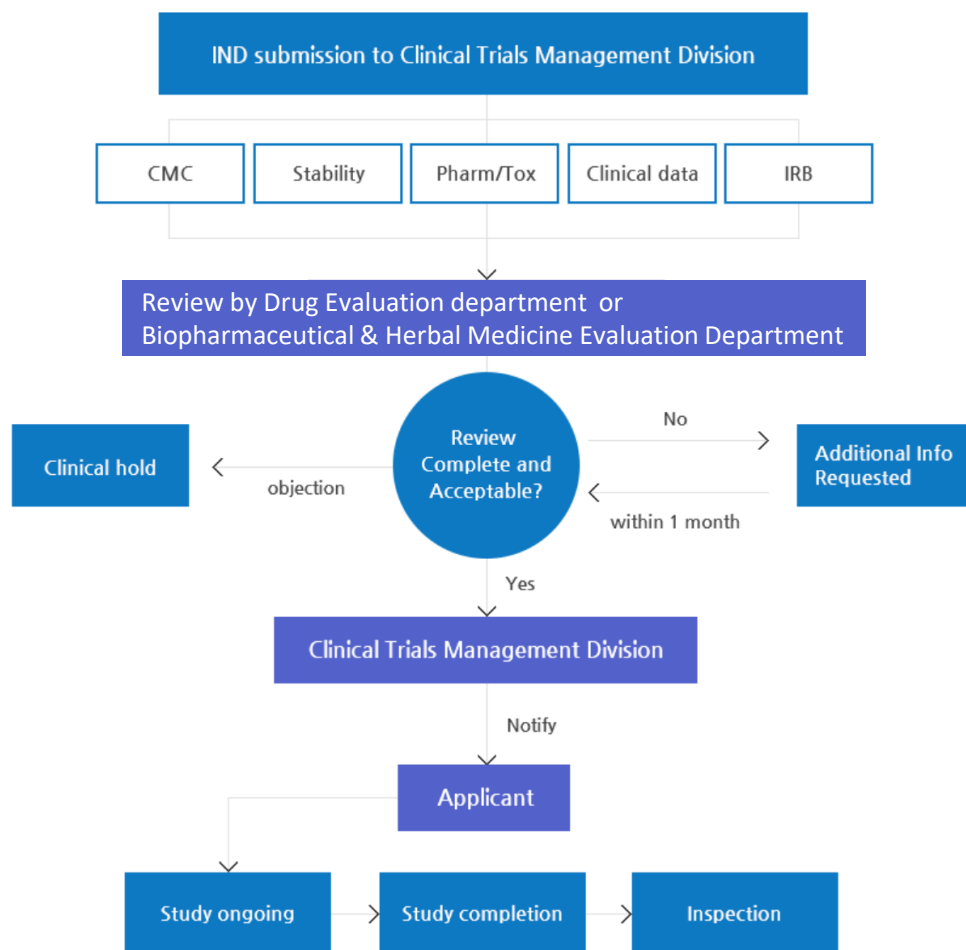


Status of CDISC in Korea

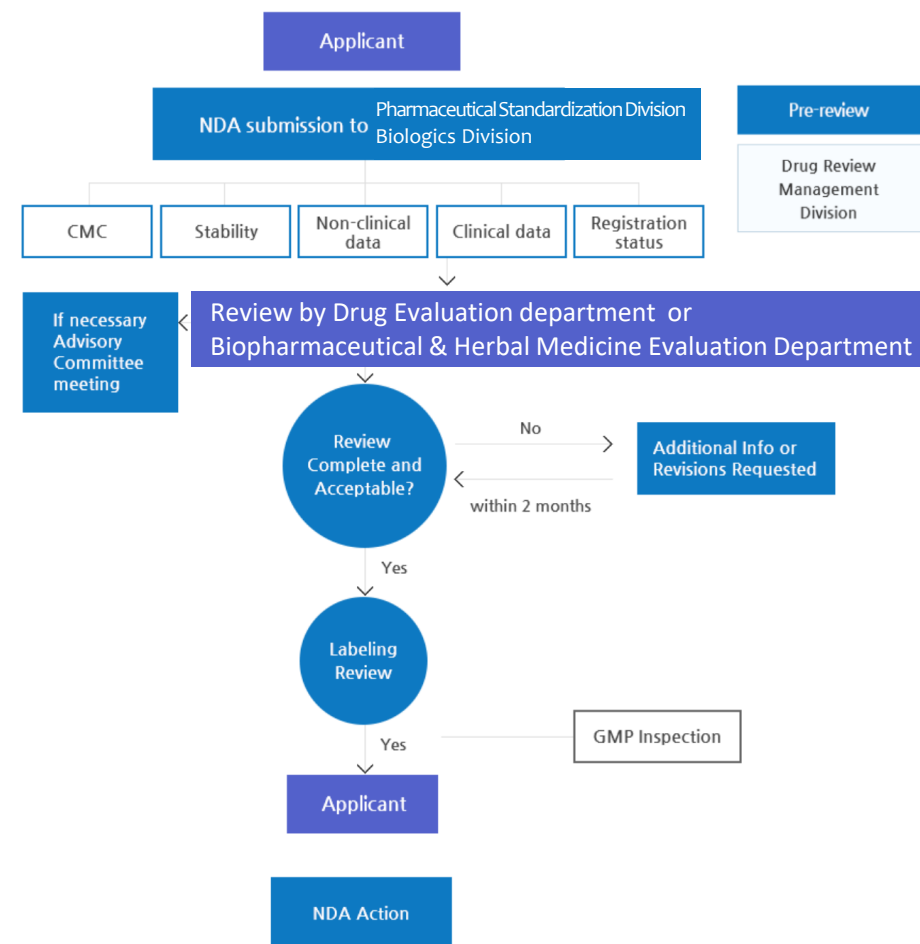
2. NDA/BLA Approval Process & Data Submission

NDA/BLA Approval Process

IND (Investigational New Drug Application) Review Process

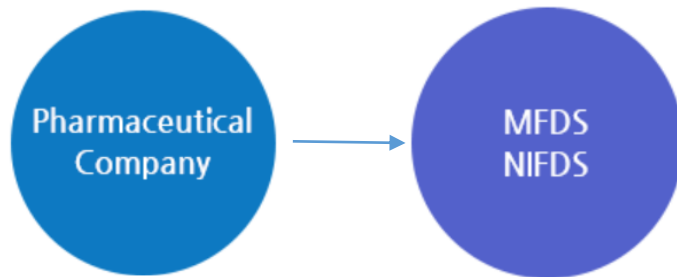


NDA (New Drug Application) Review Process



Data Requirements for Approval

- ▶ Dossier for IND
 - Development plan
 - Introduction
 - Data on structural identification and psychochemical and biological properties (including data for a placebo)
 - Data on non-clinical studies
 - Data on Pharmacology
 - Data on Toxicity
 - Data on clinical studies (if applicable)
 - Study protocol
 - References
 - Investigator's Brochure (IB)

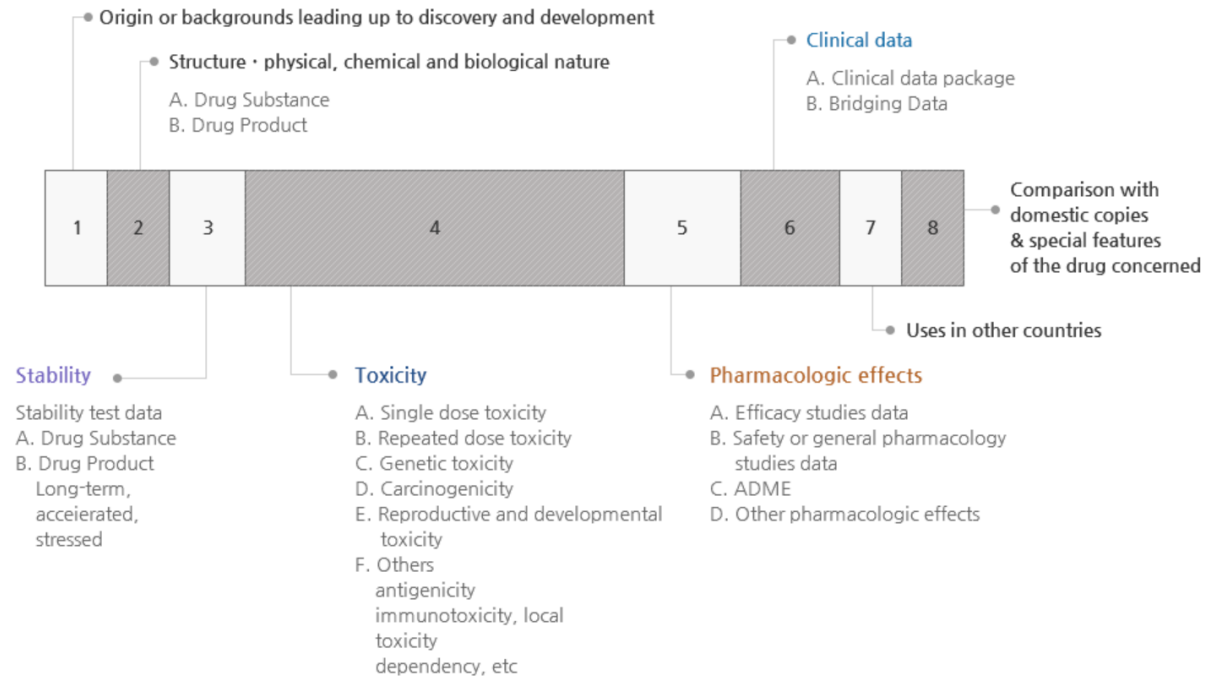


Electronic Data Submission

By 「Pharmaceutical Affairs Act」 & 「Regulation on Safety of Pharmaceuticals」(Ordinance of the Prime Ministerial)

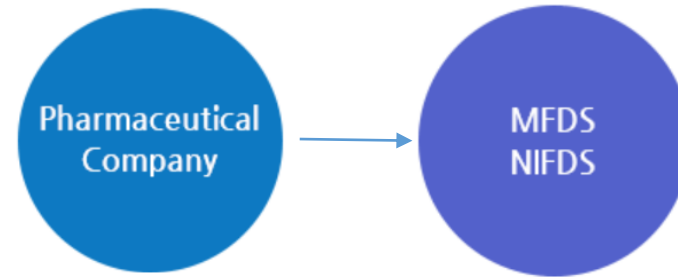
▶ Data Requirements for Approval

- ▶ New Drug (「Regulation on Safety of Pharmaceuticals」(Ordinance of the Prime Ministerial) Article 9)
 - (Review by Drug Evaluation Department) Safety & efficacy data, specifications & test methods, Drug Master Files (DMF), certificate of manufacturing and marketing(Imported Pharmaceutical) Data such as name and address of manufacturers of active pharmaceutical ingredients
 - (Review by Other Departments) Evaluation data of conducting of Good Manufacturing Practice (GMP)



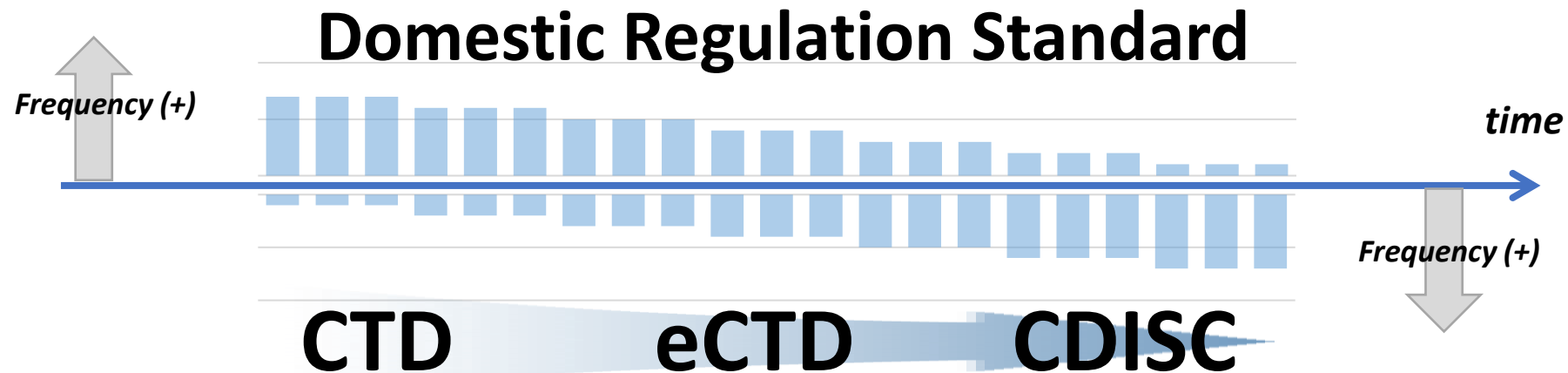
Dossier for Safety & Efficacy Evaluation

Electronic Data Standard for International Harmonization in Korea



Electronic Data Submission

By 「Pharmaceutical Affairs Act」 & 「Regulation on Safety of Pharmaceuticals」 (Ordinance of the Prime Ministerial)



Status of CDISC in Korea

3. Regulations related to eCTD/CDISC

Regulations, etc. related to CTD/eCTD submission

- ✍ 「PHARMACEUTICAL AFFAIRS ACT」 Articles 31, 42
- ✍ 「Regulation on Safety of Pharmaceuticals, Etc.」 (Ordinance of the Prime Ministerial) Articles 4, 8, 9, 10
- ✍ 「**Regulation for Pharmaceutical Approvals, Notifications and Reviews**」 **Articles 6**
- ✍ 「Regulation for Biopharmaceutical Approvals, Notifications and Reviews」 Articles 8
- ✍ 「Regulation for Herbal Medicines Approvals, Notifications and Reviews」 Articles 7
- ✍ 「Regulation for Novel Product Approvals, Notifications and Reviews」 Articles 6
- ✍ 「Regulation on Approval of Clinical Trial Plans for Pharmaceuticals」 Articles 5
- ✍ 「Guidelines for processing and managing clinical trial electronic data」
- ✍ 「Guidance Document for Electronic Common Technical Document (eCTD) Compilation (Applicant's Instruction Manual)」

Article related to CDISC submission

Regulation for Pharmaceutical Approvals, Notifications and Reviews

Ministry of Food and Drug Safety Notification No. 2021-90
Partially Amended and Enforced on Nov 11, 2021

Chapter I General Rules

Article 1 (Purpose)

This regulation is intended to stipulate detailed information regarding target articles, types of data submitted, description tips, requirements, and exemption scopes of data, specifications and controls, etc. for the manufacturing and marketing approval or notification of pharmaceuticals, the importing approval or notification of pharmaceuticals, and the review of safety and efficacy, specifications, test methods of drugs in accordance with Articles 31, 35, 42, and 76 of the "Pharmaceutical Affairs Act (PAA)," Articles 4, 5, 8 through 13, 39, 40, and 57 through 59 of the "Regulation on Safety of Pharmaceuticals, Etc.," Articles 18, 21, and 24 of the "Narcotics Control Act" Articles 32 and 33 of "Enforcement Decree of the Narcotics Control Act" and Article 19 of the "Rare Diseases Management Act".

Article 6 (Preparation of Common Technical Documents)

- (1) In spite of Article 5, for new drugs and drugs requiring data submission and drugs falling under Article 25
- (2) 3 (except for orphan drugs, high pressure gas for medical use, radiopharmaceuticals, drugs for export, and other products that are not directly applied to humans) among prescription drugs, shall be prepared in the Common Technical Document (CTD) format. In these cases, detailed preparation tips are governed by Annex 3 Preparation Method for Drugs CTD. However, for items beyond items stated above, the CTD format should still be used.
- (3) The pharmaceutical approval application or notification prepared in accordance with Articles 4 and 6 may be submitted as electronic documents according to the preparation tips, when the Minister of Ministry of Food and Drug Safety notifies eCTD preparation tips. In this case, nonclinical study data and clinical study data may be submitted by applying Clinical Data Interchange Standards Consortium.

Module 1 ADMINISTRATIVE INFORMATION AND PRESCRIBING INFORMATION

- 1.1 Table of contents of Module 1
- 1.2 Copy of the manufacturing and marketing approval and notification application or the importing approval or notification application

Status of CDISC in Korea

4. Efforts to Domestic Implementation for CDISC standard

Efforts to Domestic Implementation for CDISC standard

- ✓ 1st ISP for stand alone eCTD/CDISC management system(2013)
- ✓ eCTD/CDISC Submission System construction(2014)
- ✓ 2nd ISP for integrate 25 systems include eCTD/CDISC system(2017)
- ✓ Pharmaceutical integrated information system construction(2018~)
 - ❖ Including eCTD/CDISC Submission System
- ✓ Amendments Regulation for Pharmaceutical Approvals to include CDISC standards(2021)
- ✓ Civilian Government Engagement Advisory Group(2023~)
 - ❖ CDISC Sample Submission Technical Pilot

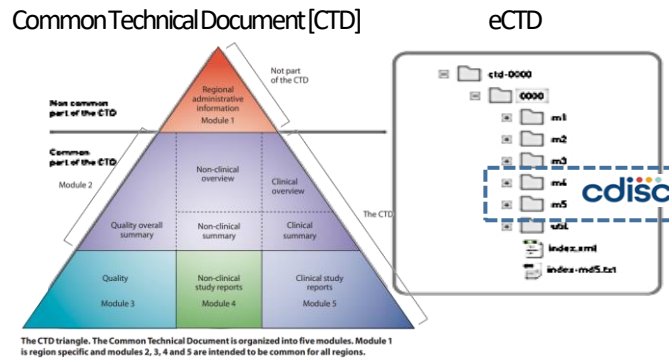
Status of CDISC in Korea

**5. Submit an eCTD or Standardized Data
to the MFDS**

Submit eCTD and CDISC to the MFDS

Phase 1. Create CTD/CDISC

- ① Create CTD documents and PDF files for submission
- ② Complete CDISC for submission



Phase 2. Create eCTD include CDISC & Prepare for Submission

< Create eCTD >



- ① Install and run eCTD software by MFDS
- ② Create eCTD with CTD documents(PDF files)
- ③ Mount CDISC during the eCTD creation process
- ④ Verification in software and finish all process

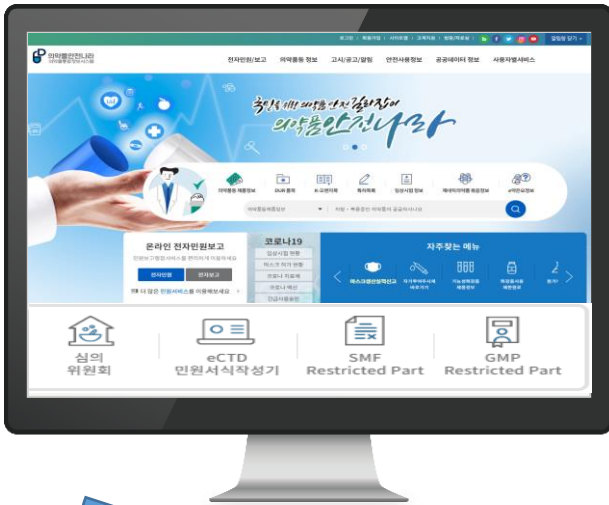
< Temporarily upload to my account >

- ① Log-in to the 'https://nedrug.mfds.go.kr'
- ② Temporarily upload eCTD file
 - * my page > file upload > eCTD file management
- ③ Verification on website

Phase 3. Electronic Application

- ① Fill out the electronic application
- ② Attach eCTD file already uploaded to my account
- ③ Complete the application form and go to next process(fee payment, etc)

eCTD software by MFDS



Download

64 bit OS
64 bit JAVA



The screenshot shows the 'New Project' dialog box in the eCTD software. The fields are filled with the following information:

- Project name: CDISC- test
- Project directory: C:\CDISCtesteCTD
- Company: MFDStest
- Product: test
- eCTD version: 3.2.2
- sequence: 0000
- module selection: m1, m2, m3, m4, m5
- CDISC: m4, m5
- DMF: 제출용양식

Buttons: 확인 (Confirm), 취소 (Cancel)

Message: 새 프로젝트 [CDISC- test]가 생성됩니다.

The screenshot shows the file explorer view of the eCTD software. The project structure is as follows:

- CDISC- test
 - 0000 [3.2.2] - 0000
 - m1
 - m2
 - m3
 - m4
 - 42- stud- rep
 - 421- pharmacol
 - 422- pk
 - 423- tox
 - 43- lit- ref
 - datasets**
 - m5
 - 52- tab- list
 - 53- clin- stud- rep
 - 531- rep- biopharm- stud
 - 532- rep- stud- pk- human- biomat
 - 533- rep- human- pk- stud
 - 534- rep- human- pd- stud
 - 535- rep- effic- safety- stud
 - 536- postmark- exp
 - 537- crf- ipl
 - 54- lit- ref
 - datasets**

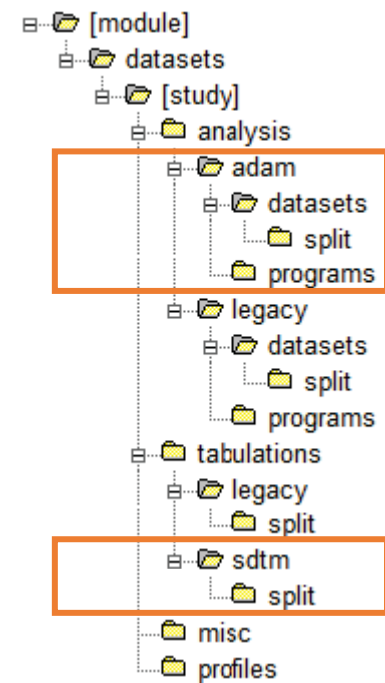
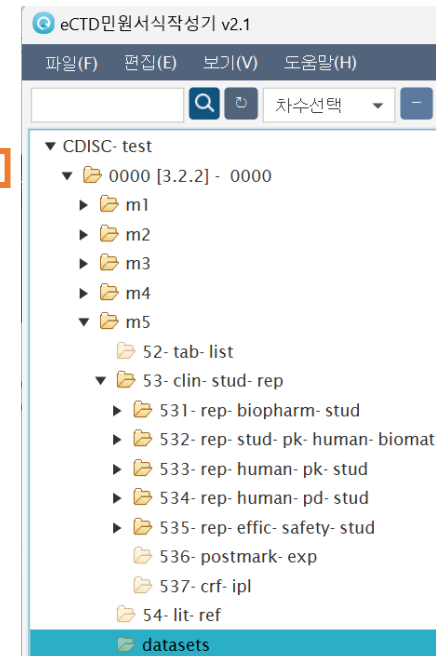
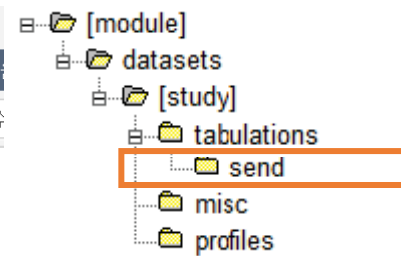
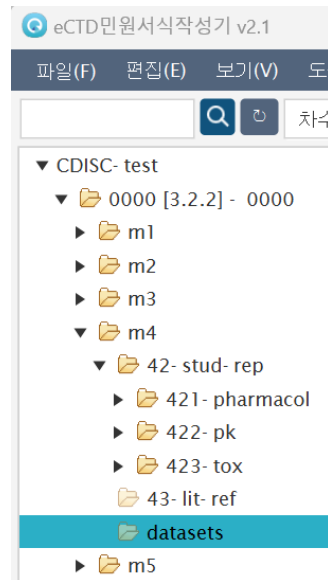
Location of CDISC in eCTD (in Phase 2)

eCTD M4

eCTD M5

< Internal structure of eCTD submission file Folders and required utility files >

Folder	Files	Definition
	(e123456.zip)	eCTD submission filename(e-Identifier)(ex: e123456)
0000		A folder with a sequence name indicating the number of submissions as a four-digit number.(ex: 0000)
	index.xml	index file ICH standard
	index-md5.txt	MD5 checksum file
m1		Module 1 Application details and administrative information folder
	kr	Korean domain codename(kr) folder
	kr-regional.xml	Index file of M1 with MFDS standard configuration applied
m2		Module 2 Submission data overview and summary folder(ICH CTD m2)
m3		Module 3 Quality evaluation data folder (ICH CTD m3)
m4		Module 4 Non-clinical trial data folder (ICH CTD m4) CDISC (SEND)
m5		Module 5 Clinical trial data folder (ICH CTD m5) CDISC (SDTM ADaM)
util		ICH eCTD specification utility folder
	dtd	ICH eCTD specification DTD and schema folder
	ich-ectd-3-2.dtd	ICH standard DTD file applied from m2 to m5
	kr-regional-1-0.dtd	MFDS standard DTD file applied to m1
	style	Stylesheet folder for the ICH eCTD specification
	ectd-20.xsl	ICH standard style sheet file applied from m2 to m5
	kr-regional.xsl	MFDS standard style sheet file applied to m1



Temporarily upload eCTD to my account (in Phase 2)

Electronic Application

Log-in to my account

국민을 위한 의약품 안전 길라잡이

의약품 안전나라

무엇을 찾고 계신가요?

치방·복용중인 의약품이 궁금하시나요?

1 / 2 < || >

의약품 부작용 피해구제 신청

이제 **“의약품안전나라”**에서 신청하세요!

바로가기

공지사항 | 회수/판매중지 | 안전성시험속보

2022 11.1 시스템 점검 작업에 따른 의약품안전나라 접속 지연 안내

의약품안전나라의 안정적이고 지속적인 서비스를 지원하기 위해 의약품안전나라 시스템 서버 점검을 실시하고자 합니다. 서버점검 작업으로 해당 시간 동안 접속 지연 등 시스템 장애...

- 시스템 점검 작업에 따른 의약품안전나라 접속 지연 안내 2022-11-10
- 공공기관 고객만족도 조사 관련 개인정보 제3자 제공사정 알림 2022-11-07
- 전자허가증 서비스 변경 사항 안내 2022-10-28

자가투여주사제 | 기능성화장품제품정보 | 화장품사용제관련료 | 첨가제정보 | 의약품상호작용 | 통합자료실 | 용어사전

행정처분정보 | 품목허가정보 | DUR 성분고시

2022 11.02 1.이너핸드클리너(에탄올),2.포루투나세티아이지겔(에탄올),3.아르...
○ 의약품 '1.이너핸드클리너(에탄올),2.포루투나세티아이지겔(에탄올),3.아르밍세티아이지겔(에탄올),4.닥터클린세티아이지겔(에탄올),5.손진한손소독제겔(에탄올),6.리겐에스핸드겔...'

1.이너핸드클리너(에탄올),2.포루투나세티아이지겔(에탄올),3.아르밍세티아이지겔(에탄올),4. 닥터클린세티아이지겔(에탄올),5.손진한손소독제겔(에탄올),6.리겐에스핸드겔... 2022-11-02

1.덴트릭스지약, 2.덴트릭스하브테라피치약, 3.덴트릭스더블케어치약, 4.삭제, 5.삭제 등 1건 - ... 2022-09-06

온라인 전자민원보고

민원보고행정서비스를 편리하게 이용하세요

전자민원 > 전자보고 >

코로나19(Covid-19)

임상시험현황 | 마스크허가현황

코로나치료 | 코로나백신

마이페이지

나의민원 | 나의보고내역 | 파일업로드관리

eCTD관리

민원첨부파일

위임관리

특허등재료

1:1문의내역

내정보 맞춤설정

회원정보수정

시스템 접속 기록

전자허가증

eCTD관리

출발번호 eCTD요약정보

제출기간 - 업로드상태 전체

접수상태 전체 검증 상태 전체

총 10건

순번	자정일자	삭제예정일	eCTD요약정보	eCTD버전	검증상태	검증보고서	접수상태	접수번호	신청인
1	2021-11-10	-	정10mg	-	검증완료(190)	[eCTD 검증 보고서]	검토	2020-11-10	
2	2019-11-10	-	리스	-	검증완료(190)	[eCTD 검증 보고서]	처리완료	2019-11-10	
3	2019-11-10	-	200밀리그램 CTD	-	검증완료(190)	[eCTD 검증 보고서]	처리완료	2019-11-10	
4	2019-11-10	-	100밀리그램	-	검증완료(190)	[eCTD 검증 보고서]	처리완료	2019-11-10	

Electronic Application (in Phase 3)

Electronic Application

Log-in to my account

로그인 | 회원가입 | 사이트맵 | 고객센터 | 법령/자료실

의약품안전나라
의약품통합정보시스템

전자민원/보고 | 의약품등 정보 | 고시/공고/알림 | 안전사용정보 | 공공데이터 정보 | 사용자별서비스

국민을 위한 의약품 안전 길라잡이
의약품 안전나라 무엇을 찾고 계신가요?
의약품등제품정보

치방·복용중인 의약품이 궁금하시나요?

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의약품안전나라의 안정적이고 지속적인 서비스를 지원하기 위해 의약품안전나라 시스템 서버 점검을 실시하고자 합니다. 서버점검 작업으로 해당 시간 동안 접속 지연 등 시스템 장애...

- 시스템 점검 작업에 따른 의약품안전나라 접속 지연 안내 2022-11-10
- 공공기관 고객만족도 조사 관련 개인정보 제3자 제공사정 알림 2022-11-07
- 전자허가증 서비스 변경 사항 안내 2022-10-28

자가투여주사제 | 기능성화장품제품정보 | 화장품사용제관련료 | 첨가제정보 | 의약품상호작용 | 통합자료실 | 용어사전

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○ 의약품 '1.이너핸드클리너(에탄올),2.포루투나세티아지젤(에탄올),3.아르밍세티아지젤(에탄올),4.닥터클린세티아지젤(에탄올),5.손신한손소독제겔(에탄올),6.리겐에스핸드겔...'

1.이너핸드클리너(에탄올),2.포루투나세티아지젤(에탄올),3.아르밍세티아지젤(에탄올),4. 닥터클린세티아지젤(에탄올),5.손신한손소독제겔(에탄올),6.리겐에스핸드겔... 2022-11-02
1.덴트릭스지약, 2.덴트릭스허브테라피치약, 3.덴트릭스더블케어치약, 4.착제, 5.착제 등 1건 - ... 2022-09-06

온라인 전자민원보고
민원보고행정서비스를 편리하게 이용하세요

전자민원 | 전자보고

코로나19(Covid-19)
임상시험현황 | 마스크허가현황
코로나치료 | 코로나백신

Electronic Application

전자민원/보고

전자민원

- 전자민원 이용안내
- 전자민원신청
- 전자결재및수수료안내
- 임상시험신청자동등록
- 화장품연구기관등록
- 의약품 불순물 관련 자료 검토
- 회의신청

전자보고

이상사례

코로나19 관련 신고·승인 및 보고

의약품 부작용 피해구제

전자민원신청

Select Pharmaceutical Product

민원사무검색 | 전체 | 의약품

민원사무목록 | Application Type | 민원사무안내

45	단순민원	의약품제조업신고	의약품등의 제조나 수입을 위한 품목허가(의약품 등의 안전에 관한 규칙 제4 조제3호 및 제5호를 제외함)를 받고자 하는 자가 식품의약품안전처장에게 신청하는 민원사무입니다.
46	단순민원	의약품 부작용 피해구제급여 지급 신청	
47	단순민원	의약품 불순물 자료 검토	
48	복합민원	의약품(의약품)제조(수입)품목변경허가.신고	
49	복합민원	의약품(의약품)제조(수입)품목허가.신고	

의약품품목허가-신약

민원사무분류

1차분류명	2차분류명	선택	수수료 및 처리일수
<input checked="" type="radio"/> 의약품품목허가	<input checked="" type="radio"/> 신약	<input type="checkbox"/> - 연유	수수료 807,000
<input type="radio"/> 생물약품품목허가	<input type="checkbox"/> 회귀의약품	<input type="checkbox"/> - 안정성	처리일수 25
<input type="radio"/> 한약(생약)제제등품목허가	<input type="checkbox"/> 회귀의약품국내임상수행	<input type="checkbox"/> - 기시	
<input type="radio"/> 한약재품목허가	<input type="checkbox"/> 수출용의약품	<input type="checkbox"/> - DMF	
<input type="radio"/> 의약품품목허가	<input type="checkbox"/> 기본	<input type="checkbox"/> - 대면심사	
<input type="radio"/> 의약품품목신고	<input type="checkbox"/> 신약	<input type="checkbox"/> - GMP	
		<input type="checkbox"/> - GMP(외제)	

민원신청

Electronic Application (in Phase 3)

전자민원/보고 > 전자민원 > 전자민원신청 ☆ 자주 사용하는 메뉴를 즐겨찾기 하세요! > 온라인도움말

전자민원신청

의약품등록허가-신약

- * 표시된 부분은 필수 입력항목입니다.
- * 업적이 신청종ial 경우에는 업소포장에서 '업허가신청중' 버튼을 클릭하십시오
- * 수수료: 식약의약품안전저장이 고시한 금액(수수료를 납부하여야 접수 처리됩니다.)
- * 대표자의 휴대폰 번호를 입력하시면 접수 및 허가 진행사항을 대표자 휴대폰 SMS로 받을 수 있습니다.
- * 하단의 추가정보(구비서류 버튼은 임시 저장 이후에 등록 가능합니다.)

신청인(대표자)

대표자	Representative	휴대폰	Cell Phone number
제조소의명칭	name of Manufactory	업소허가번호	
제조소 주소	address of Manufactory		

민원신청 상세내역

제표사항	원료약품 및 그 분량	제조원/DMF/제조방법	RMP	성상	효능효과	응용용량	사용상의주의사항
제품명	Product name						
제품명(영문명)	Product name(English)						
허가신고구분	허가	원제/원료구분	- 선택 -				
품목구분	의약품	분류번호	전체				
전문/일반	전문의약품	개발표제명					
마약류분류	- 선택 -	마약류구분	제조	수입	수출		
단일/복합	단일제	개량여부	개량신약	해당없음			
두여정보	- 선택 -						
생동정보여부		생동성시험정보	삭제	해당없음			
기타	<input type="checkbox"/> 표본제조기준 <input type="checkbox"/> 위탁생동(허여)						
입상시험 자료공통이용	<input type="checkbox"/> 해당 <input type="radio"/> 주관 <input type="radio"/> 참여 (1번 2번 3번)	주관업체 허가품목명	품목기준 코드				
	주관업체 품목 허가 접수번호	주관업체					
	주관업체 품목허가 여부(허가 미허가)	자료동의일자					
공동개발 신고 (약사법 부칙 제11조)	<input type="checkbox"/> 해당 <input type="radio"/> 주관 <input type="radio"/> 참여	공동개발신고 접수번호					

특허권계 해당없음

추가 삭제

상답이력 > 해당없음

순번	접수번호	질의제목	업체명	신청인	상답일자

- * 신청민원이 과거 신청취하 또는 반려회신 받은 이력이 있는 경우 해당 접수번호를 기재하시기 바랍니다.
- * 의약품(신약 또는 제1의약품)의 경우(허가전 보합용자 총시행)을 위한 식약처에서 신청용으로 자료연계에 동의합니다.
- * 신약 또는 개량신약의 경우 통 신청서류에 대한 민원실명피 개피를 포함합니다.
- * 민원신청시, eCTD 여부를 반드시 선택하고 필요시 eCTD를 첨부하여야 합니다. 예 아니요
- * 본포장에 연계업자 대상인 경우, 등록(민원)신청서 제출 완료 양식을 다운로드 하여 부가서류에 첨부하여야 합니다.
- * 민원신청시, 자가점검표를 작성하여야 합니다.(임시저장 후 작성 가능)

민원신청 자료제출

Restricted Part 자료제출 유무 제출유무

자료제출마감 예정일자

신청서

파일업로드 리스트

- 1. 마이페이지 > 회원정보수정에서 파일 업로드/다운로드 프로그램 사용 여부를 수정할 수 있습니다.
- 2. 화면에서 파일을 드래그해서 올리거나 파일을 업로드가 가능합니다.
- 3. 구비서류는 한글, 워드, pdf, jpg 형식의 파일로 변환하여 첨부하시기 바랍니다. 그 외 형식의 파일은 오류가 발생할 수 있습니다.

전자우편: 민원처리과정에서 발생하는 민원자의 의견을 메일로 통해 전달받기 원하는 경우 기재해주세요.
휴대폰번호: 민원신청 내용의 처리 진행사항을 안내받기 원하는 경우 기재주세요. (시스템 상황에 따라 SMS가 발송되지 않을 수 있습니다.)

민원정보

민원명	의약품등록허가-신약	처리기간	25
수수료	807,000	처리부서	허가총괄담당관
수령방법	전자우편 수령으로 수령방법 선택이 필요합니다.	접수번호	20230002052

담당자(원제)

담당자성명		전화번호	02-410-9067
휴대폰번호	민원신청 상황 알림을 위한 휴대폰 번호 수집에 동의하십니까? <input type="radio"/> 예 <input type="radio"/> 아니요	전자우편	pharmyps@hanmi.co.kr

담당자(원료)

담당자성명		전화번호	
휴대폰번호		전자우편	

DMF 임시저장 구비서류 민원신청

Whether to submit eCTD

1. Select Yes/No
2. Attach eCTD file already uploaded to my account

submit data for domestic regulation standard

Electronic Application (in Phase 3)

✓ First Submission

민원신청 상세내역

제품사항 원료약품 및 그 분량 제조원/DMF/제조방법 RMP 성상 효능효과 용법용량 사용상의주의사항

제품명

제품명(영문명)

허가신고구분 허가 신고 완제/원료구분 - 선택 -

품목구분 의약품 분류번호 전체

전문/일반 전문의약품 일반의약품 개발목표제품

마약류분류 - 선택 - 마약류구분 제조 수입 수술

단일/복합 단일제 복합제 개발여부 개량신약 해당없음

투여경로 - 선택 - - 선택 - - 선택 -

생동정보여부 생동성시험정보 삭제 해당없음

생산유형 자사제조 위탁제조 동시제조 기타 표준제조기준 위탁생동(여야)

* 동 신청인원이 과거 신청허가 또는 반려회신 받은 이력이 있는 경우 해당 접수번호를 기재하시기 바랍니다. 접수번호

* 의약품(신약 또는 허귀의약품의 경우)허가전 보험증제 중시진행중을 위한 식약처에서 심평원으로 자료연계에 동의합니다. 도움받 도움받

* 신약 또는 개량신약의 경우, 본 신청폼에 대한 민원성명회 개최를 희망합니다.

* 민원신청시, eCTD 여부를 반드시 선택하고 필요시 eCTD를 첨부하여야 합니다. 예 아니오 도움받

* 필요·관계·연계업무 대상인 경우, 중복(신원)신청서 제출 필요·영역을 구분하여 구비서류에 첨부하여야 합니다. 도움받

* 민원신청서, 자가점검표를 작성하셔야 합니다.(임시저장 후 작성 가능) 자가점검표 작성

민원정보

민원명	의약품등록허가	처리기한	25
수수료	204,000	처리부서	-선택하세요-
수령방법	3.22부터 전자허가증 시행으로 수령방법 선택이 필요합니다.	접수번호	20210081250

✓ Supplementary Submission

신청인

업소명/관련단체명

구분 -선택하세요- 허가번호

주소

대표자 전화번호

+ 추가 - 삭제

제조구분	명칭	제조국	소재지	책임자	전화번호	책임자E-mail	비고

* 민원신청시, eCTD 여부를 반드시 선택하고 필요시 eCTD를 첨부하여야 합니다. 예 아니오 도움받

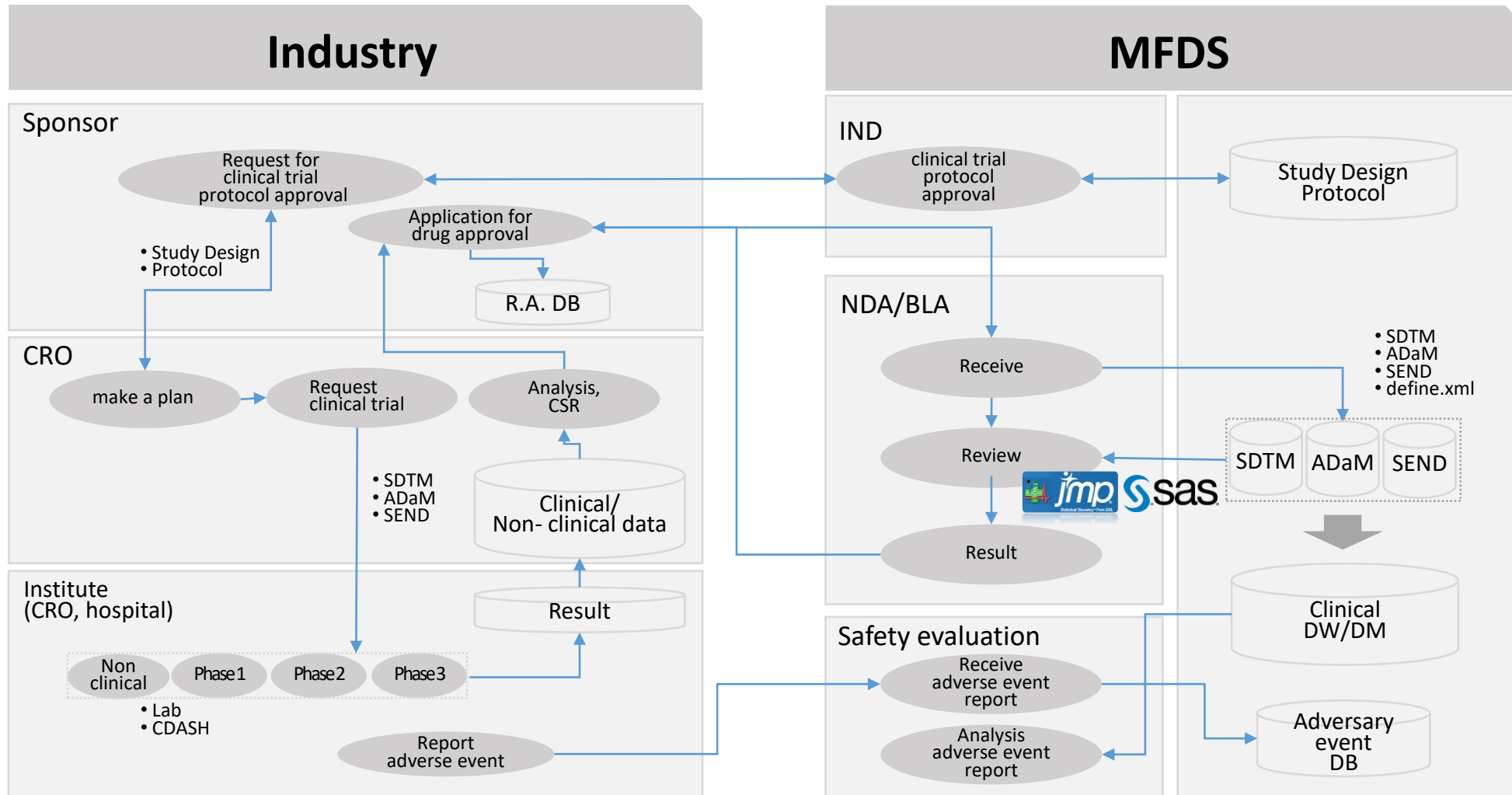
민원신청 상세내역

DMF 정보 자료제출

제 제 정 보 투여경로 -선택하세요- -선택하세요- -선택하세요-

일반명

Workflow between Industry and MFDS



Small feature of eCTD in KR

MFDS

- ✓ e-identifier of eCTD is **under** electronic application registration number
- ✓ Application details : **Not only** list in eCTD leaf, one should fill out the electronic application form
- ✓ Store separate documents and materials not defined in advance within eCTD, **but also can be submitted outer eCTD**

FDA, etc.

- ✓ e-identifier of eCTD is the same as application registration number
- ✓ Application details : only list in eCTD leaf
- ✓ Store separate documents and materials not defined in advance within eCTD

Civilian Government Engagement Advisory Group

- ✓ **(Purpose)** Communication and collaboration with major policy users, including the establishment of CDISC guidelines tailored to the domestic pharmaceutical industry situation
- ✓ **(Period/Cycle)** '23.8. ~ / Twice a year, semiannually
- ✓ **(Member)** Government side 10, Civilian side 17, total 27.

MFDS

Ministry of Food and Drugs Safety

NIFDS

National institute of Food and Drug Safety
Evaluation

KIDS

Korea Institute of Drug Safety and Risk
Management

KPBMA

Korea Pharmaceutical and Bio-Pharma
Manufacturers Association

KRPIA

Korean Research-based Pharma Industry
Association

KoBIA

Korea Biomedicine Industry Association

KSQA

The Korean Society of Quality Assurance

K3C

CERTARA




CDISC Sample Submission Technical Pilot

Summary of Pilot Status

- ✓ **(Preparation) '23. April~'24. April**
 - ❖ Internal consultation, recruitment of participating companies, system configuration, arrange items, preparing company's sample submission materials
- ✓ **(Implementation) '24. May ~ November**
- ✓ **(Participating companies) 6 companies supported, 3 companies conducted**
- ✓ **(Submission) SDTM, ADaM, SEND submitted for one item each of diabetes, hyperlipidemia, and cancer**
- ✓ **(Confirmation) synthetic drug/biologics & statistics review department personnel**
 - ❖ Provided technical support from the pharmaceutical policy department

CDISC Sample Submission Technical Pilot

✓ CDISC sample list

Company	Indication	CDISC Standards	categories	Evaluation Department
	Diabetes	SDTM ADaM SEND	synthetic drug	Bioequivalence Evaluation Division Pre-Submission Consultation Division
	hyperlipidemia	SDTM ADaM	synthetic drug	Cardiovascular and Neurology Products Division Pre-Submission Consultation Division
	cancer (non-small cell)	SDTM ADaM	Biologics	Recombinant Protein Products Division Pre-Submission Consultation Division

CDISC Sample Submission Technical Pilot

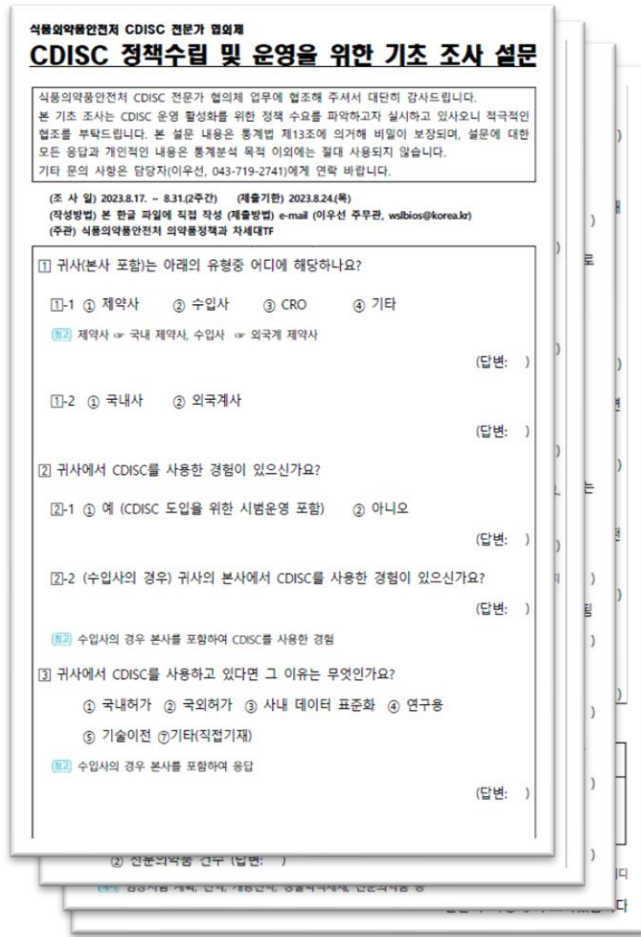
Results

- ✓ **Applicants can submit CDISC materials through the MFDS Industry system for electronic application submission, and reviewers can review CDISC submissions through dedicated software.**
 - ✓ (Electronic submission) The necessary information for the CDISC is prepared by the company through the guidelines issued by the CDISC.
 - * The reviewer downloads the CDISC data submitted by the applicant to a PC through the internal administrative portal and checks the CDISC data through dedicated software (JMP Clinical, SAS).
 - ** SDTMIG, ADaMIG, SENDIG, published by the Consortium for the Development of International Standards for Clinical Trials
- ✓ (Electronic submission) If CDISC is included in the eCTD, the current system does not have a problem submitting CDISC materials.

Status of CDISC in Korea

**6. CDISC Status in Domestic
Pharmaceutical Industry**

Cross-sectional survey of CDISC



< Population >

- KPBMA : 200 company**
Korea Pharmaceutical and Bio-Pharma Manufacturers Association
- KRPIA : 50 company**
Korean Research-based Pharma Industry Association
- KoBIA : 170 company**
Korea Biomedicine Industry Association
- KSQA : 70 company**
The Korean Society of Quality Assurance

< Period >

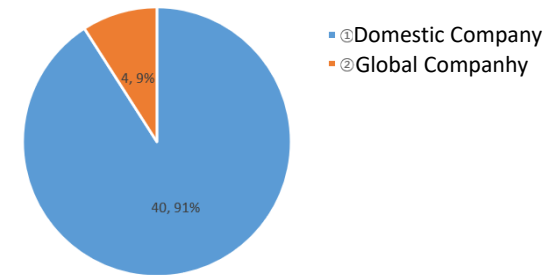
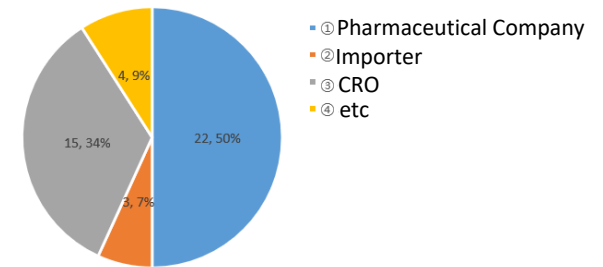
'23.8.22 ~ 9.22

< Method >

Email survey through 4 associations

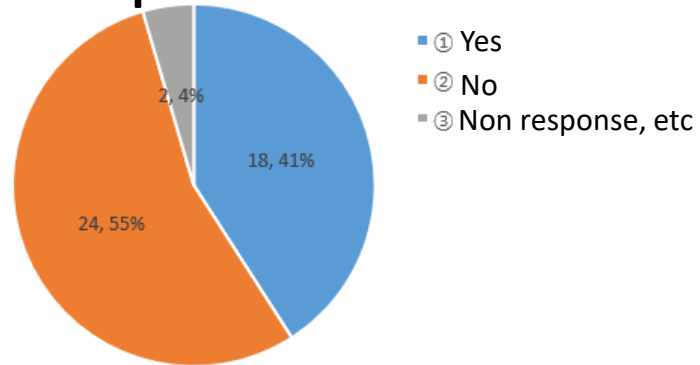
< Response >

44 companies responded (9%)

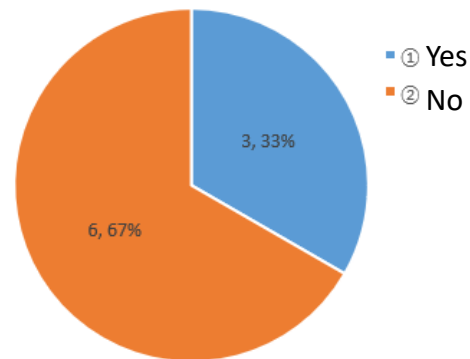


Experience & Purpose of use CDISC

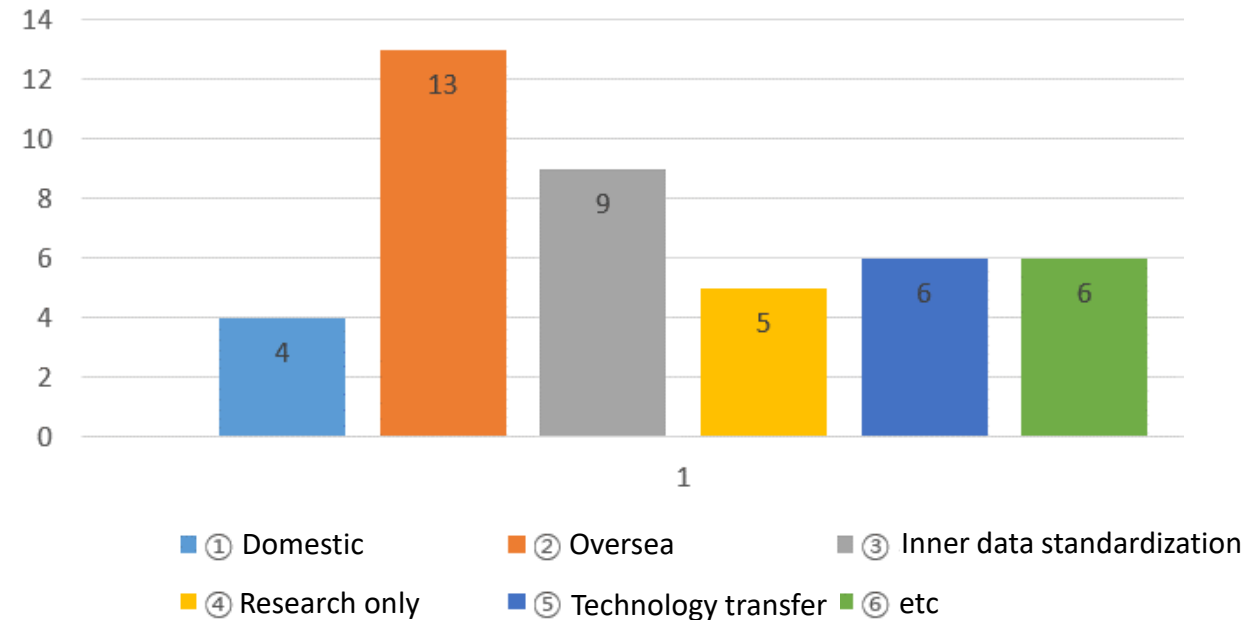
- **CDISC Utilization experience**



- **(importer) CDISC Utilization experience of headquarters**



- **CDISC Utilization Objectives in the industry**



Summary of survey results

✓ **CDISC Utilization Objectives:**

Primary objectives in the industry are, in order of priority, 'Overseas Regulatory Approval,' 'Internal Data Standardization,' 'Research,' 'Technology Transfer,' and 'Domestic Regulatory Approval.'

✓ **CDISC Utilization in 2022:**

In 2022, CDISC utilization counts are reported as 13 cases for domestic pharmaceutical companies (6 companies), 240 cases for importers (1 company), and 130 cases for CROs (5 companies).

✓ **CDISC Application in Therapeutic Areas:**

The CDISC application is diverse, covering 26 therapeutic areas, with the top 5 being 'Anticancer Drugs and Tumors,' 'Vaccines and Viruses,' 'Digestive System,' 'Cardiovascular System,' and a group of four including 'Endocrine System,' 'Metabolic Disorders,' 'Neurology,' and 'Respiratory System.'

✓ **Experience of Domestic Pharmaceutical Companies with Regulatory Agencies:**

Domestic pharmaceutical companies report having submission experience with regulatory agencies such as FDA, PMDA, EMA, and NMPA.

✓ **Preference and Concerns Regarding CDISC Regulatory Application:**

The preference for CDISC regulatory application is positive, with 79.5% expressing a 'Very Positive' or 'Positive' stance. However, concerns about the burden are notable, with 36.3% finding it 'Very Burdensome' or 'Burdensome.' Main concerns include cost, workload, manpower, and lack of experience.

✓ **CDISC Regulatory Application Scope:**

Respondents consider the application scope appropriate for 'New Drugs,' 'Clinical Trial Plans,' and 'Biological Products.' There is a desire for gradual expansion of the application scope.

✓ **Readiness and Time Estimates for CDISC Mandatory Submission:**

Only 20.4% of the industry feels immediately ready for CDISC mandatory submission, while 61% expect a significant amount of time to be spent on preparation. The average estimated time for industry readiness is around 2 years.

Status of CDISC in Korea

7. Implications and Conclusions

Implications

✓ **Industry Snapshot**

- Only 20% (6 companies) are currently ready for "immediate submission" under CDISC mandatory adoption, revealing a modest preparedness level.
- Anticipated average preparation time is around 2 years, underscoring the significant commitment required.
- Despite challenges, certain industry leaders are taking proactive steps in CDISC adoption.
- Industry acknowledges the need for substantial preparation, including specialized personnel, organizational adjustments, and budget considerations.
- Key players are already at the forefront of CDISC implementation.

✓ **Strategic Industry Approach**

- Industry prioritizes leveraging specialized knowledge and experience, with a focus on new drug development.
- Emphasis on knowledge dissemination and gradual expansion of CDISC application scope.

✓ **Stance of MFDS**

- MFDS concerns about the potential impact of immediate implementations of standardized systems.
- Call for regulatory policies balancing industry needs and compliance, including sufficient recommendation periods, gradual application, and criteria alignment with industry expectations.
- Collaborative approach suggested, involving industry stakeholders in CDISC standards formulation for mutual understanding and industry compliance.

MFDS's Position on CDISC Standards

✓ Support for CDISC Activation

- MFDS expresses support for the activation of CDISC within the industry, aiming to foster the adoption of standards.

✓ Mitigating Hurdles in Standard Adoption

- Striving to introduce minimal standards to prevent obstacles in the industry's adoption of CDISC, the agency emphasizes a facilitative approach.

✓ Collaboration with Foreign Regulatory Bodies

- While introducing minimal standards, MFDS seeks to provide sufficient information for effective communication with foreign regulatory bodies, facilitating entry into international regulatory frameworks.

✓ Consideration of Industry Environment

- Recognizing the industry's unique characteristics, MFDS aims to tailor the CDISC implementation environment to suit industry needs, emphasizing practical feasibility and efficiency.

✓ Phased Application of CDISC Standards

- MFDS acknowledges the need for considering various stages of CDISC standard application, spanning from the early stages of research to post-study data transformation. This comprehensive approach is intended to smooth the application of CDISC standards in the Korean regulatory process.

Q & A



WHO? WHERE? WHAT?
WHY? WHERE? HOW?
HOW? WHO?
WHO? WHERE? WHAT?
WHERE? WHOSE? WHY?
WHAT? WHEN?
HOW? WHO?
HOW?
WHY? WHOSE? WHEN? WHY?
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WHERE? WHAT?
WHEN?

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