Introduction of Saudi Arabia Medical Device Regulatory System

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AHWP TC Chair

Saudi Food & Drug Authority ）

Drug **Food** **Medical Device** **Pesticides** **Cosmetics** **Feeds** **Tobacco**

Saudi Food and Drug Authority (SFDA) was established under the council of Ministers resolution No (1) Dated 07/01/1424 H (March 10, 2003 G), as an independent body corporate

Medical Device Sector

Vision

To be a regionally distinguished regulatory authority for medical devices and related electronic products, working toward safeguarding the public health of Saudi Arabia.
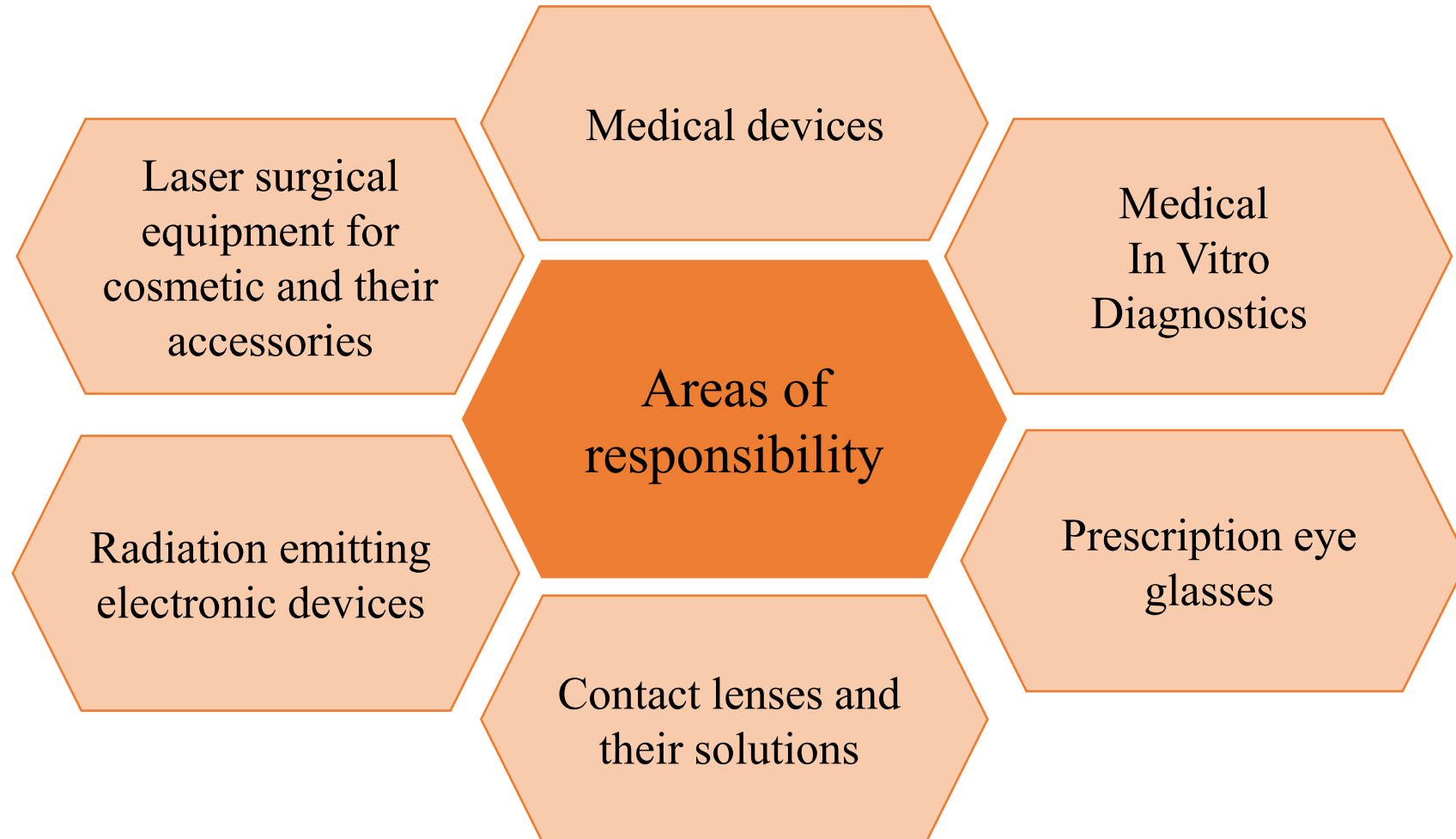
Mission

To ensure safety, effectiveness and quality of medical devices and their performance according to their intended purpose and to ensure the safety of related electronic products.
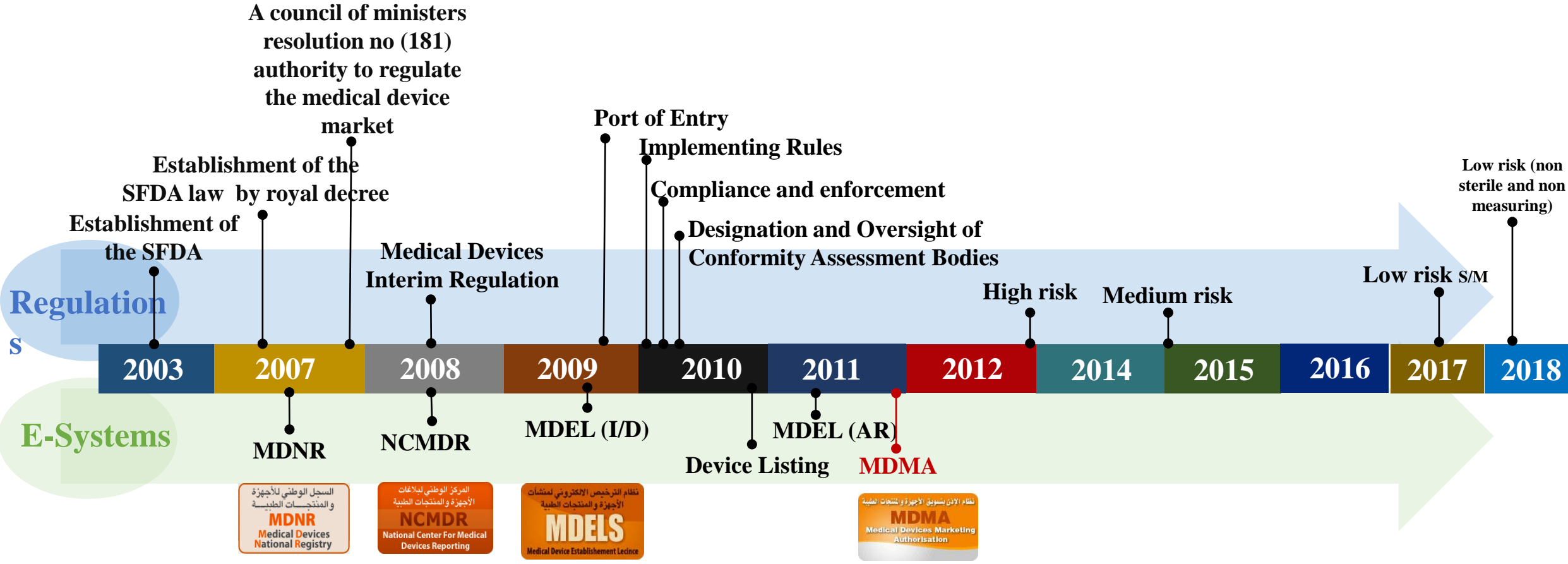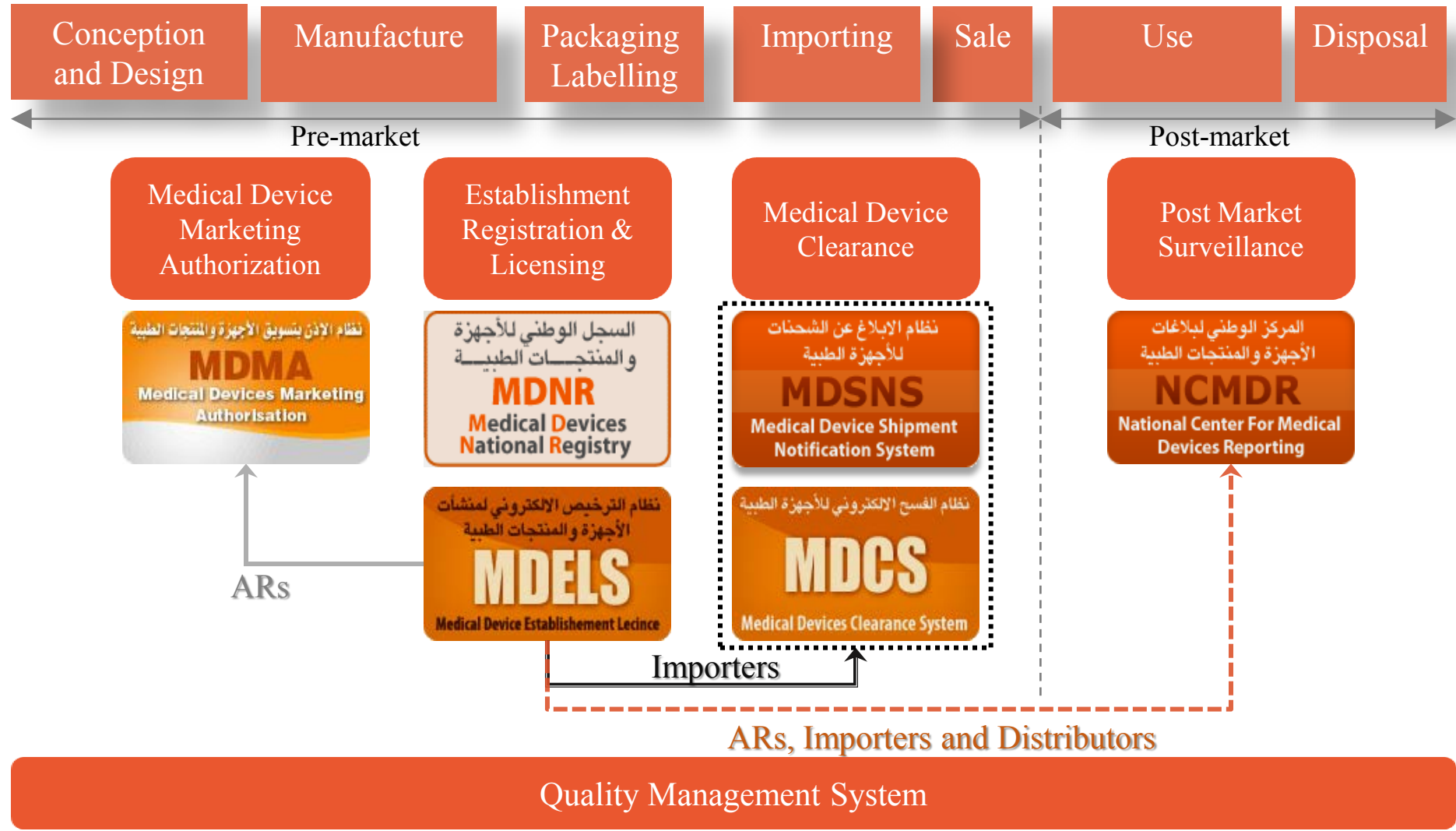
SFDA Medical Devices Regulatory Framework

Conception and Design | Manufacture | Packaging Labelling | Importing | Sale | Use | Disposal

Pre-market | Post-market

Medical Device Marketing Authorization

Establishment Registration & Licensing

Medical Device Clearance

Post Market Surveillance

نظام الاذن بتسويق الأجهزة والمنتجات الطبية
MDMA
Medical Devices Marketing Authorisation

السجل الوطني للأجهزة والمنتجــــات الطبيـة
MDNR
Medical Devices National Registry

نظام الابلاغ عن الشحنات للأجهزة الطبية
MDSNS
Medical Device Shipment Notification System

المركز الوطني لبلاغات الأجهزة والمنتجات الطبية
NCMDR
National Center For Medical Devices Reporting

نظام الترخيص الالكتروني لمنشآت الأجهزة والمنتجات الطبية
MDELS
Medical Device Establishement Lecince

نظام الفحص الالكتروني للأجهزة الطبية
MDCS
Medical Devices Clearance System

ARs

Importers

ARs, Importers and Distributors

Quality Management System

MD Sector Regional & International Participation and collaboration

1. AHWP
   - AHWP Chair 2011-2014
   - AHWP TC Co-Chair 2008-2011 reelected 2014
   - AHWP TC Chair 2014-2017 reelected 2020
   - Former Chair WG1, Chair WG6, Member STG (U&N).

2. GHTF
   - SG3 2008-2012 as AHWP TC Rep.

3. IMDRF
   - MDSAP WG 2012-2014 as AHWP TC rep.
   - Personalized Medical Devices WG as AHWP TC rep.

4. GMDN

   Member ,PAG –GMDN.

5. ISO, IEC.

   Member in various TCs.

6. Gulf Health Console- GHC

   Chair, GCC Central Medical Devices Registration Committee.

7. Gulf Standard Organization- GSO

   Chair & Secretary, TC for medical devices and supplies.

8. WHO:
   1. Group (1) : Development of a model regulatory framework for medical devices.
   2. Group (2) : Development of National Regulatory Authority (NRA) assessment tool for medical devices.
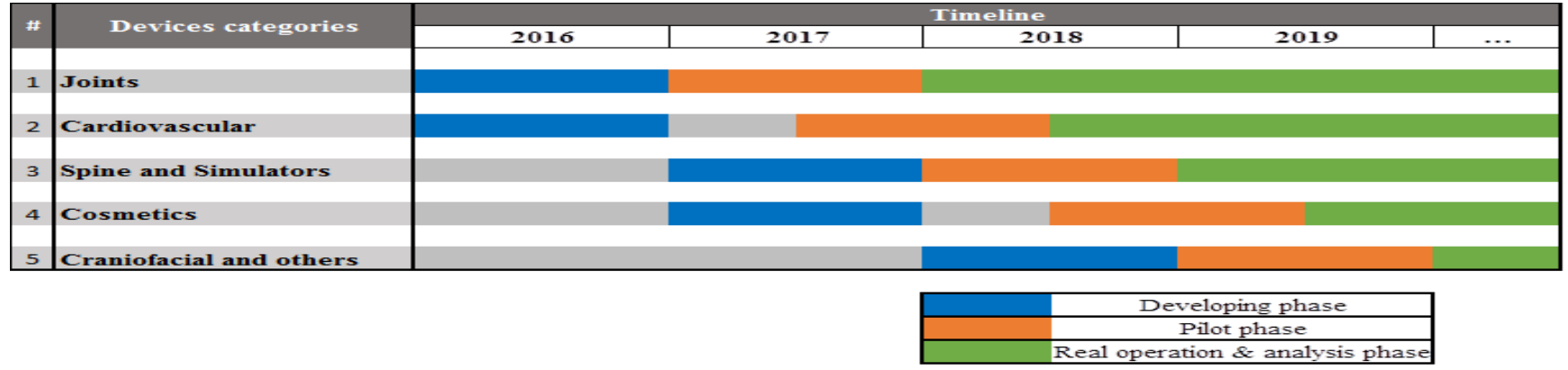
Update on SFDA Regulatory developments

- Medical Devices Interim Regulation requires local manufacturers, authorized representatives, importers, distributors, healthcare providers importing medical devices, and any party who is involved in importing medical devices, to register their establishments with the SFDA's Medical Device National Registry (MDNR) and obtain MDEL.

- To obtain marketing authorization, medical devices shall comply with the relevant regulatory requirements applicable in one or more of the jurisdictions of Australia, Canada, Japan, the USA and the EU/EFTA, and additionally with provisions specific to the KSA concerning labeling and conditions of supply and/or use. . SFDA may issue marketing authorization in accordance with SFDA requirements .

- Saudi FDA QMS

- Clinical trails (registration licensing and evaluation)

MDs Implant Registry

Is: An organized system that collects data for scientific, clinical, policy purposes and a specific set of demographic and health data on identifiable persons Observation on current patterns of practice w/out influencing the treatments or interventions

Advantages:

▪ Tracing & contacting implant recipients via Healthcare provider for FSN's/Recall's

▪ Monitor & capture the performance data of implanted devices (long term & short term)

▪ Credible reference database that enlists medical implants data and all related data (Scientific, health)

#	Devices categories	Timeline				
		2016	2017	2018	2019	...
1	Joints					
2	Cardiovascular					
3	Spine and Simulators					
4	Cosmetics					
5	Craniofacial and others					

	Developing phase
	Pilot phase
	Real operation & analysis phase