3DU:HOMO (E)X MACHINA

Lacey Harbour
AFDO/RAPs AI-Global Health Initiative
Manager, Regulatory Affairs Thermo Fisher Scientific



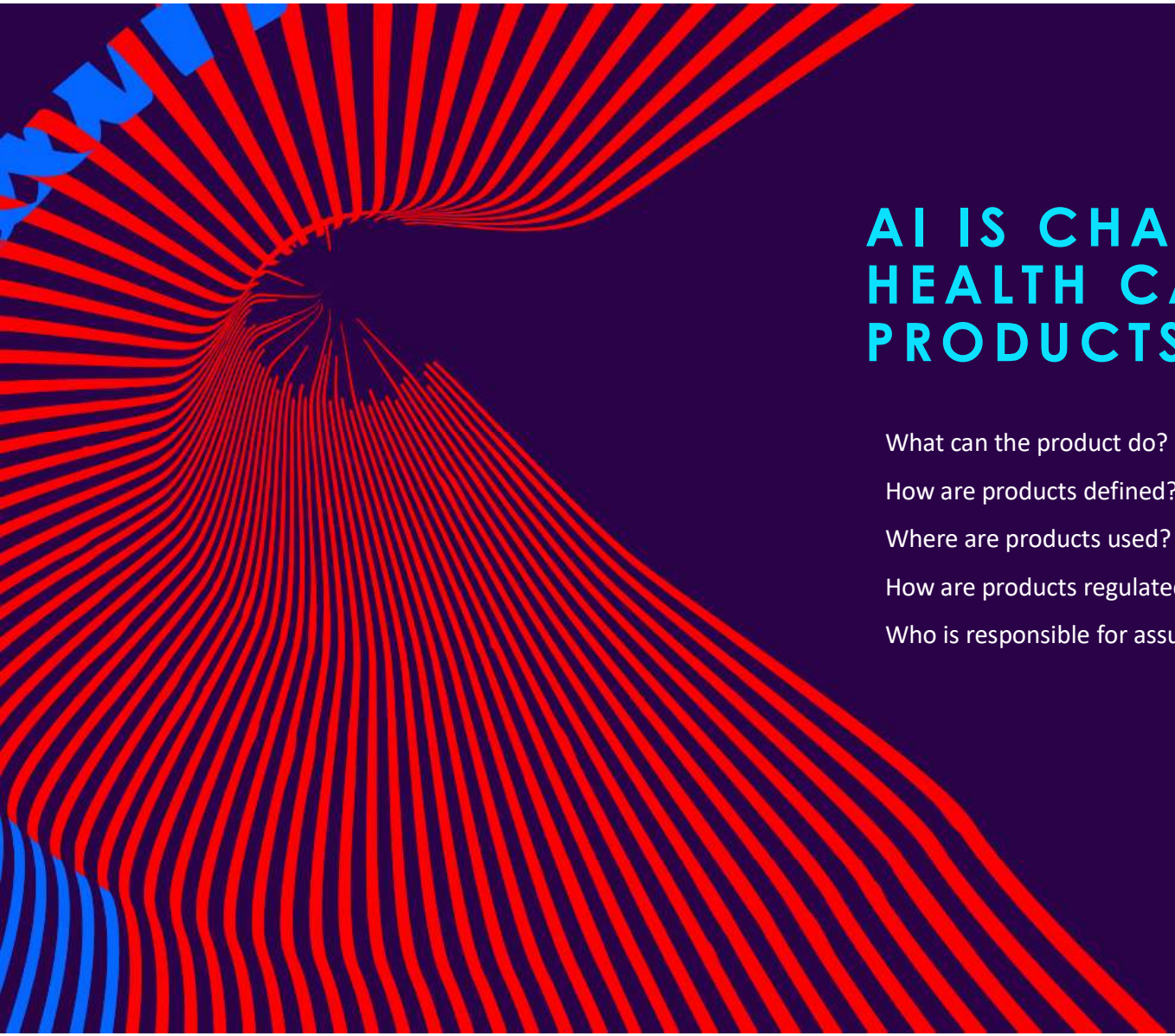
LACEY HARBOUR

Strategic Committee and WG Leader, AI-GHI

Manager, Regulatory Affairs, Thermo Fisher Scientific

- Previous RAQA Lead of the first in hospital medical device manufacturer
- AFDO/RAPS Healthcare Products Collaborative Leader – FDA Collaborative Community
    - Xavier AI World Consortium Collaborative Community
- BSI/ AAMI AI standards for medical technology-AI/ML kick off team
- AAMI published on AI
- ASME speaker on Additive Manufacturing at the Point of Care
- American Society of Clinical Pathology Certified in Molecular Biology





AI IS CHANGING HEALTH CARE PRODUCTS ECOSYSTEM

What can the product do?

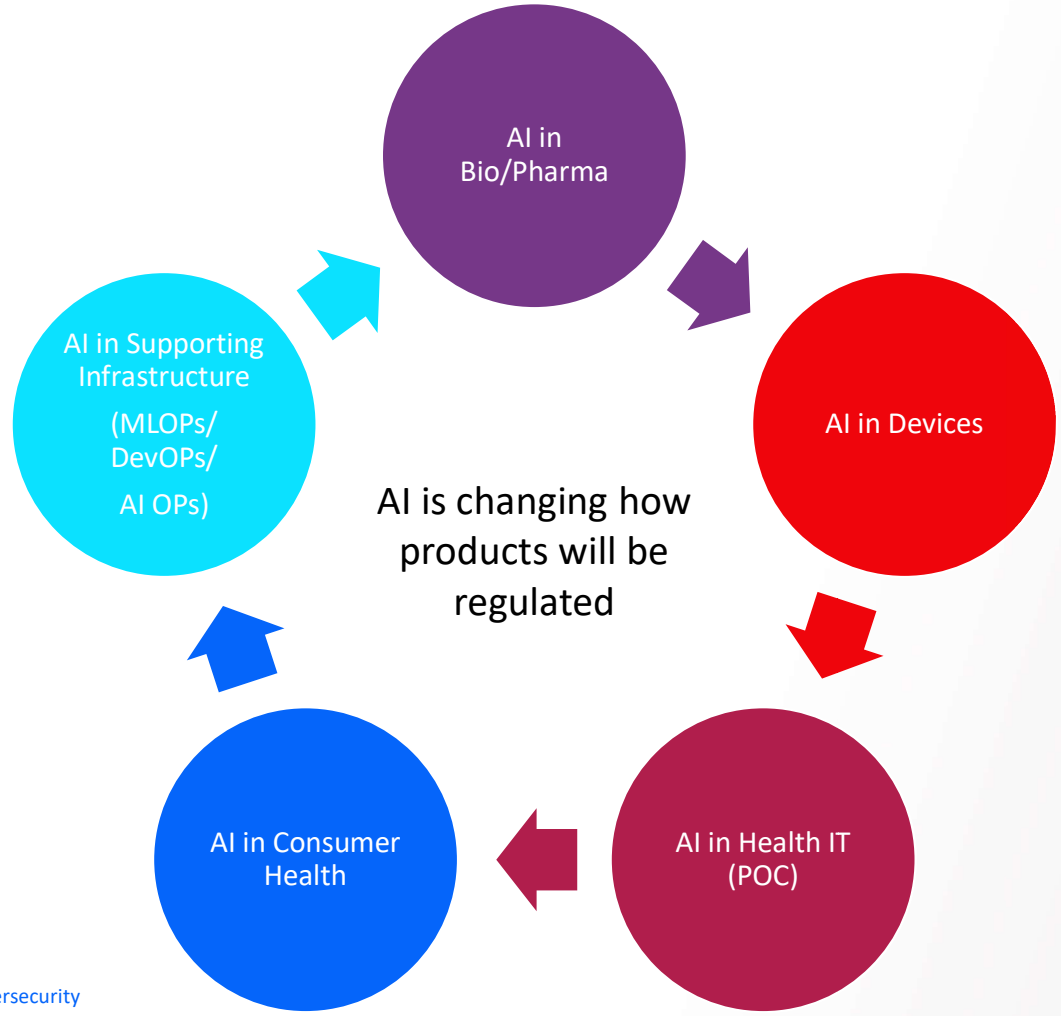
How are products defined?

Where are products used?

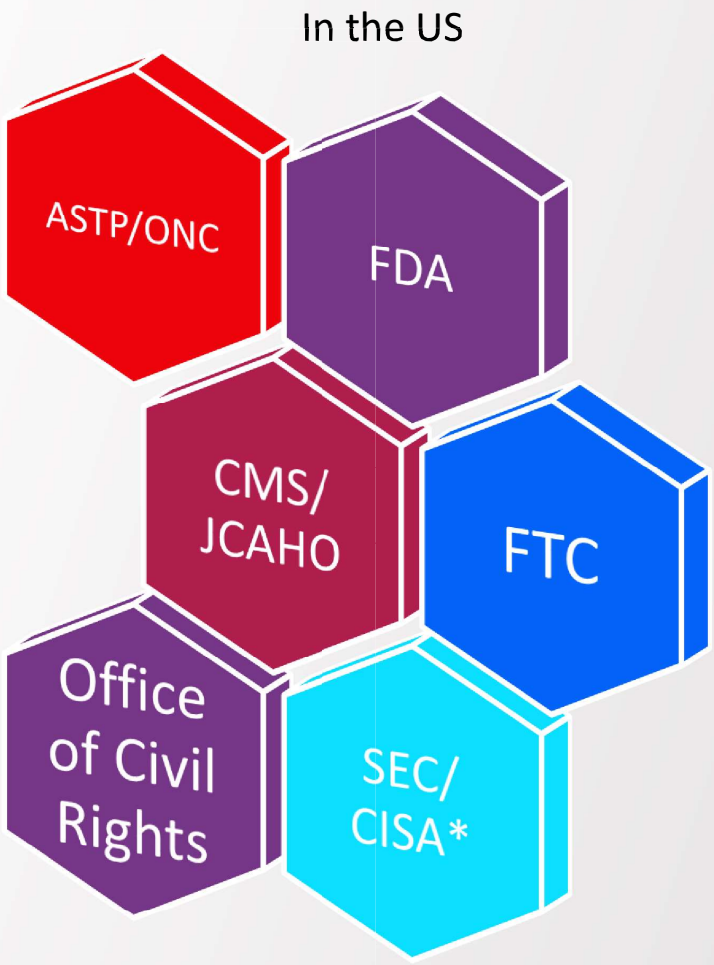
How are products regulated and by whom?

Who is responsible for assuring quality, S&E and security?

Health AI Ecosystem



*For cybersecurity



AI IS CHANGING THE MDM:HDO RELATIONSHIP

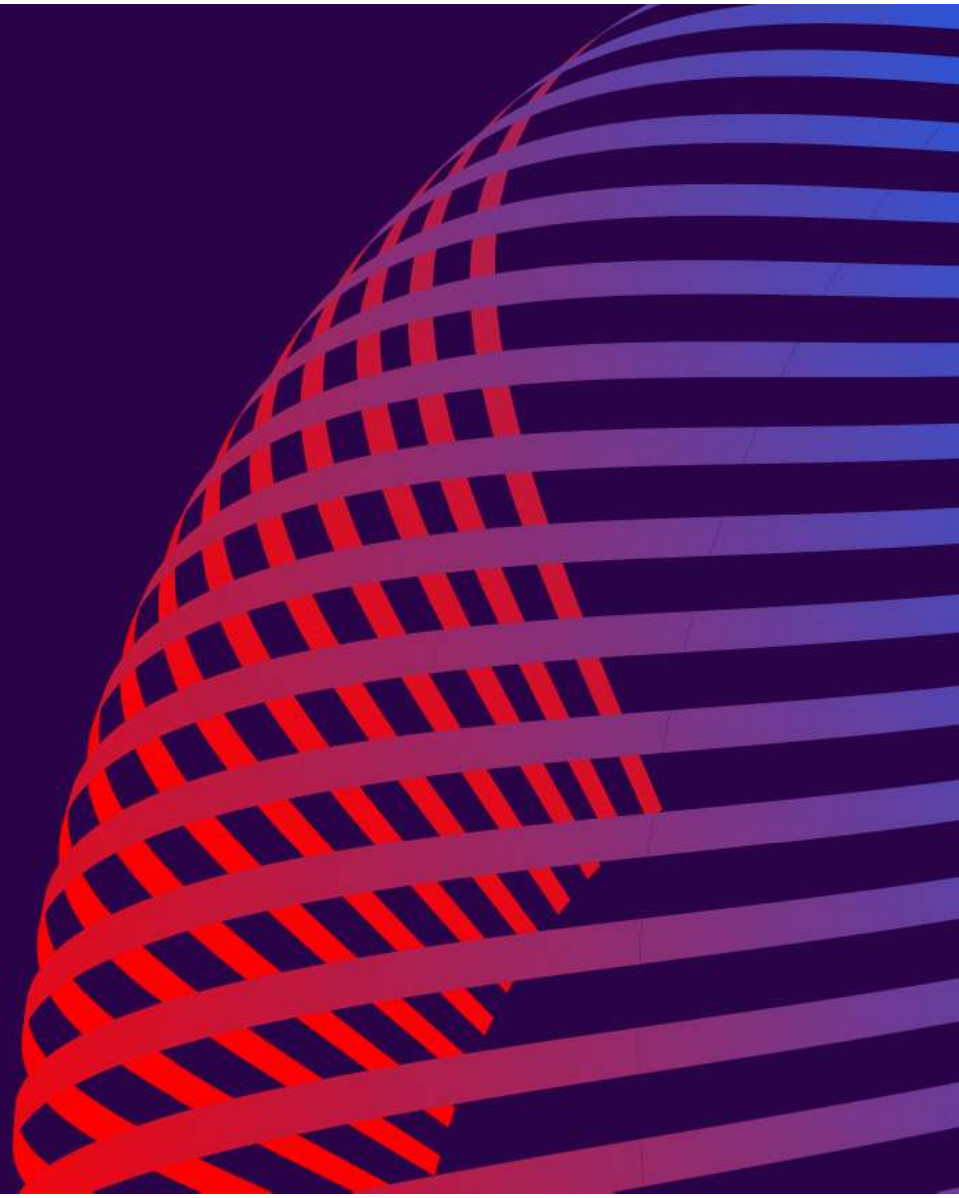
Data sharing agreements

Product transparency

Use transparency

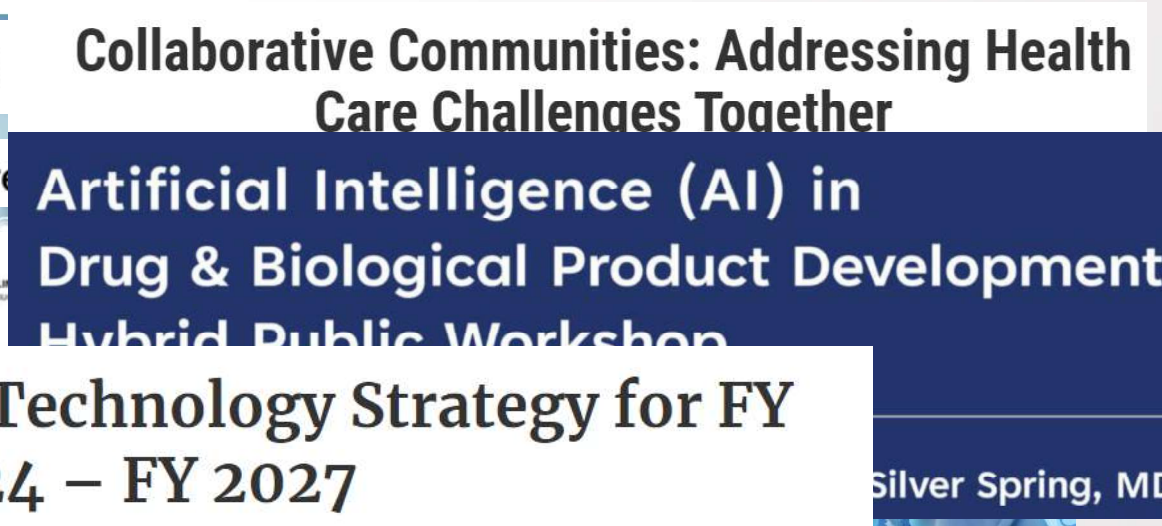
Responsibilities within agreements

Consent



FDA is Growing with Industry



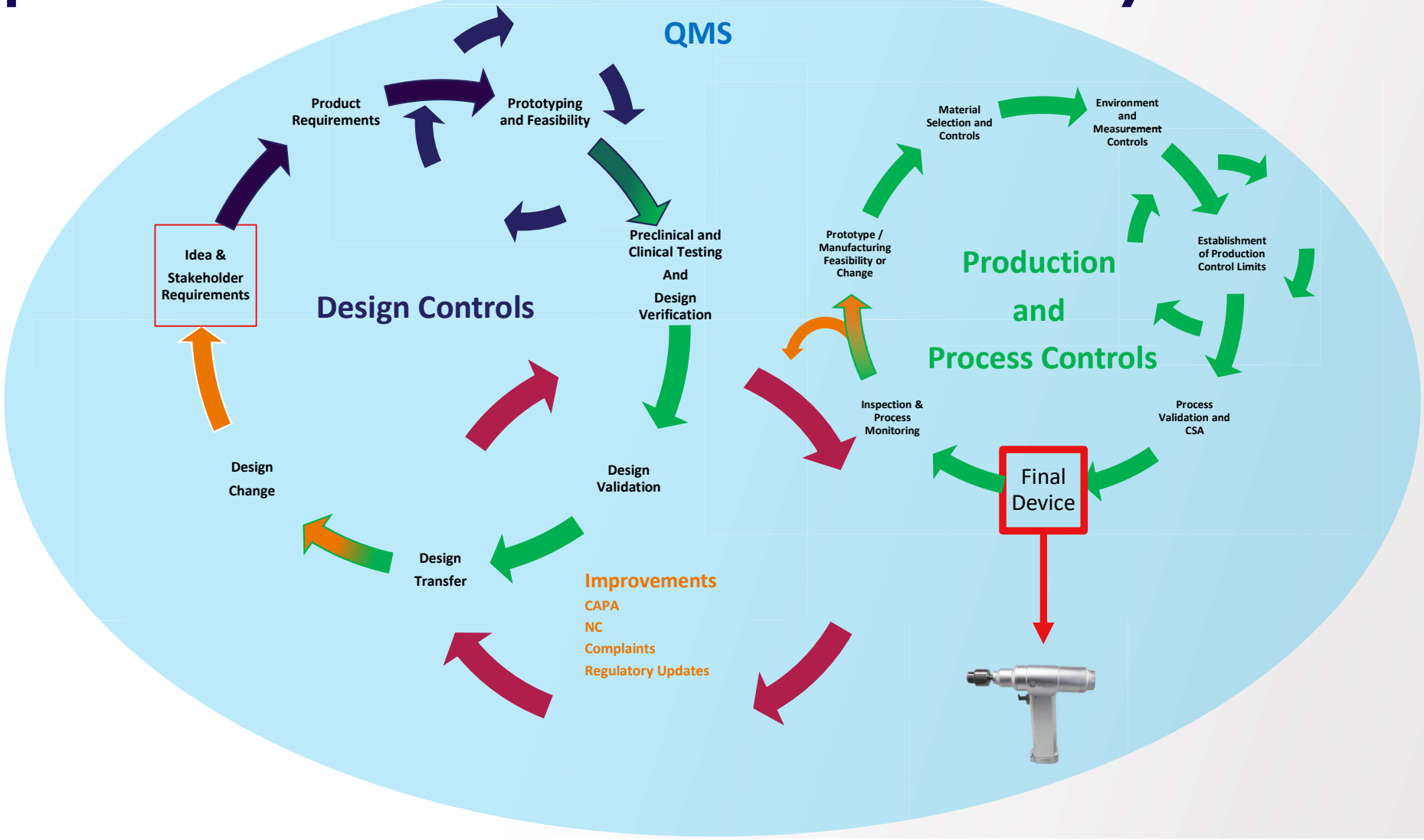




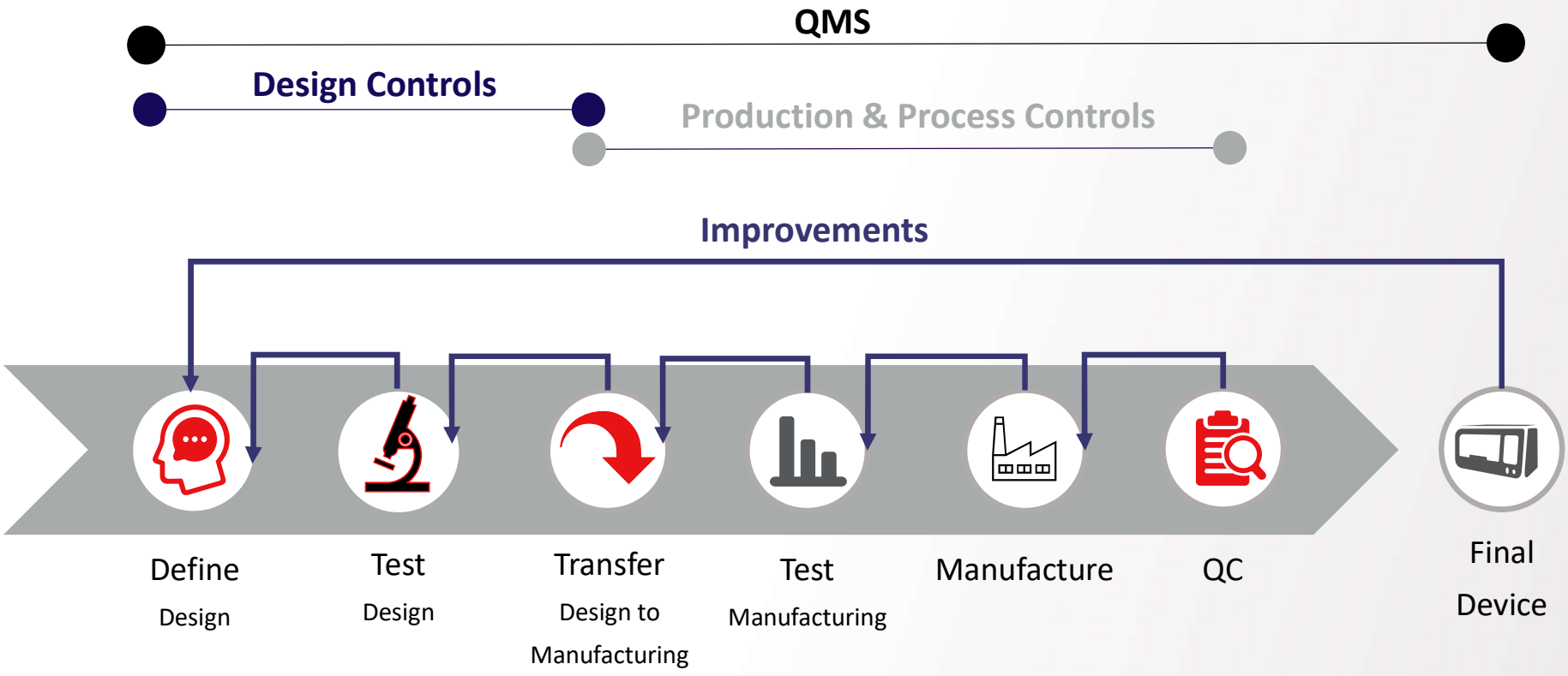




Simplified Basics of Total Product Lifecycle



Further Simplified TPLC

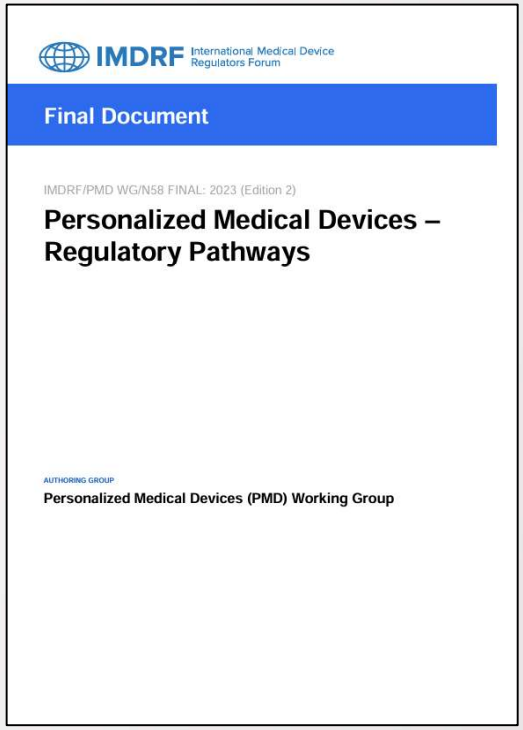


Regulatory & Growth with AI

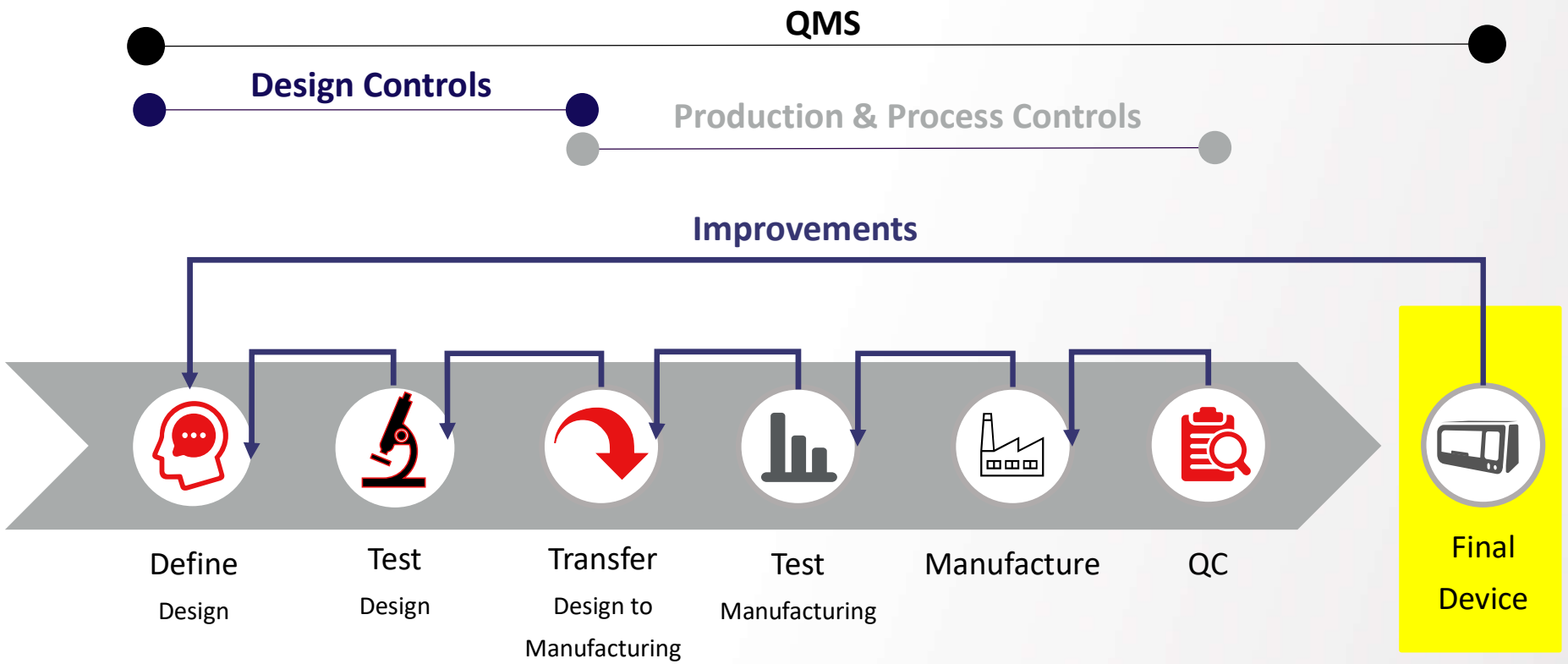
At the point of care use case

- **The Future of Medicine is Precise, Personal, and POC**
- With 3DP/ AM Applications in:
  - IVDs that decentralize lab testing
  - Bioprinting/ tissue engineering and implants
  - Oncological microfluidics (microprinting)
    - Diagnosis, modeling, and drug delivery
  - Pharmaceuticals
  - Orthopedic implants, surgical guides, and surgical models
  - Dental applications
  - Much more….

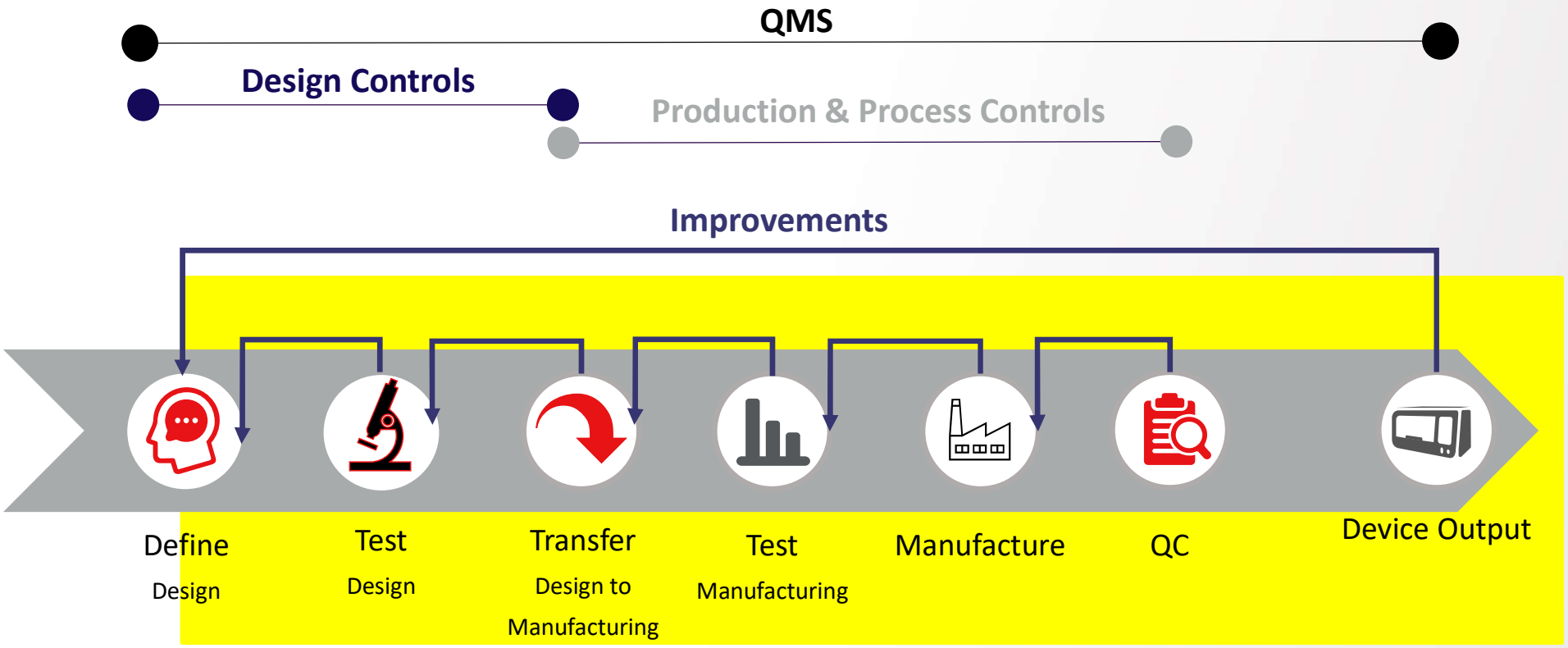




Further Simplified TPLC



Medical Device Production System (MDPS)



1 **Setting End to End Process and Limits**

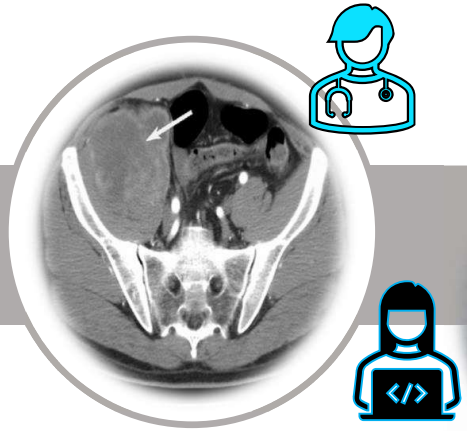
2 **MDPS = Device**



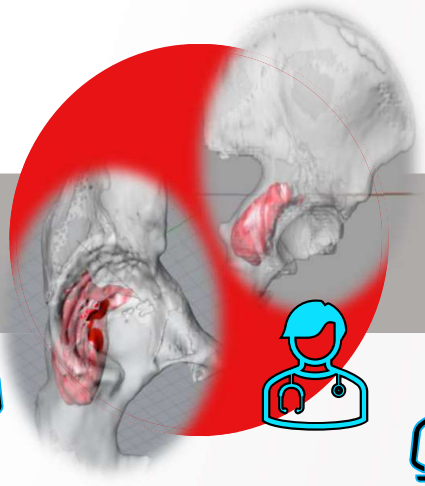
How to get a Custom/ Patient Matched Ortho Implant?



CT Scan



Health Professional Review and Segmentation

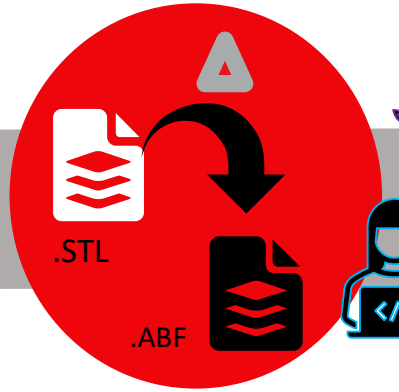


Defect Identification



Custom Development & Surgical Planning

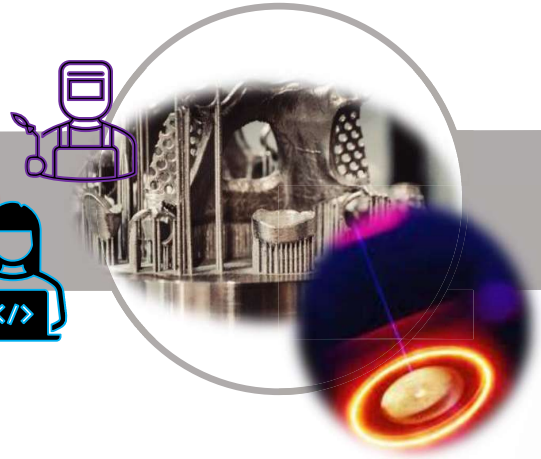
3DP Orthopedic Implant Process Cont.



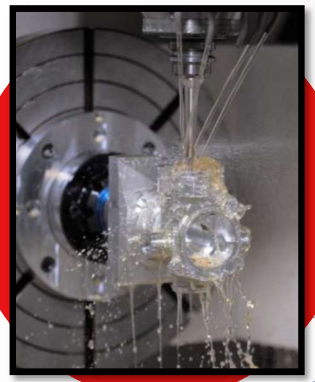
Design to Machine File(s) Conversion

&

Manufacturing Feasibility

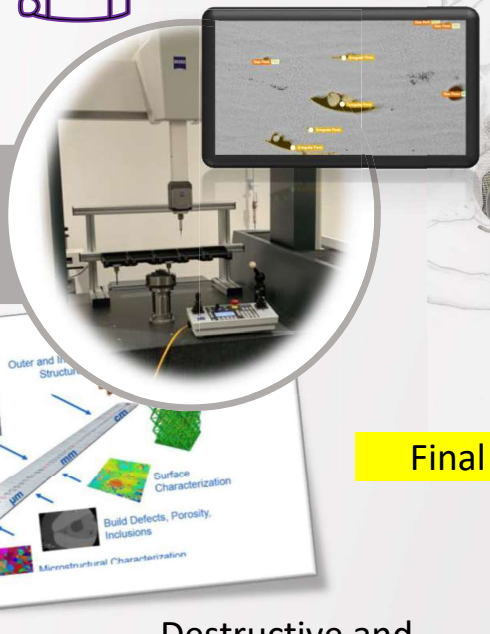


3DP Build(s)



Post Processing

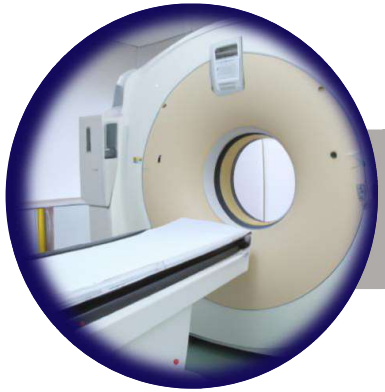
QC



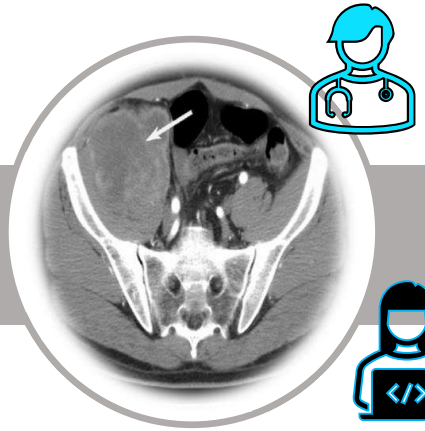
Destructive and Non-Destructive Testing



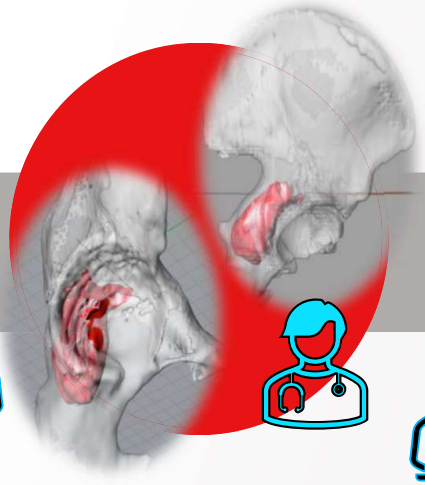
Final Product



CT Scan



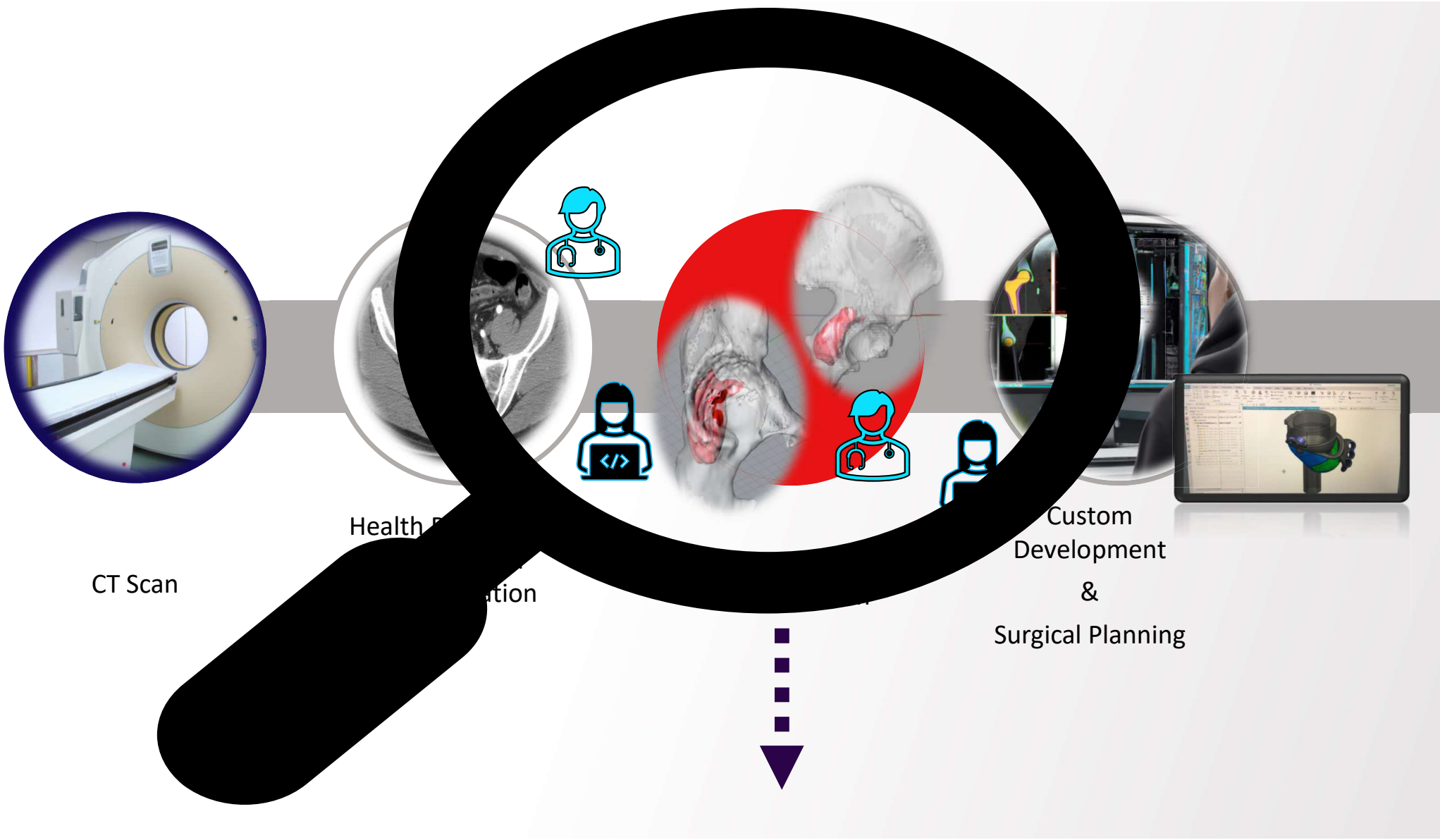
Health Professional Review and Segmentation

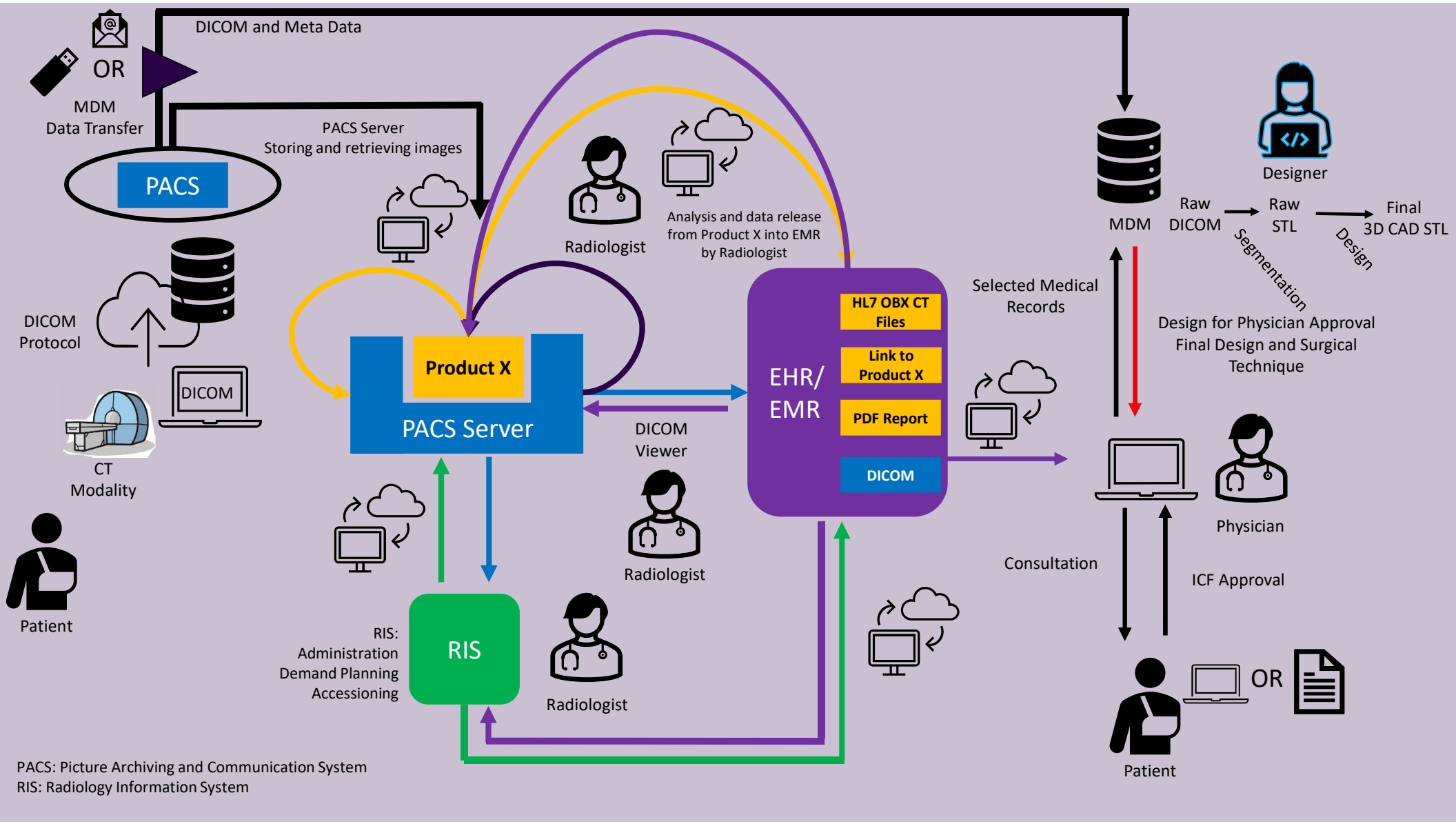


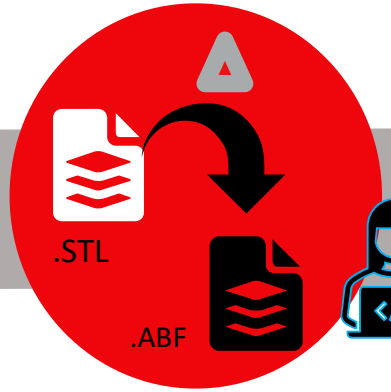
Defect Identification



Custom Development & Surgical Planning


CT Scan
Custom
Development
&
Surgical Planning

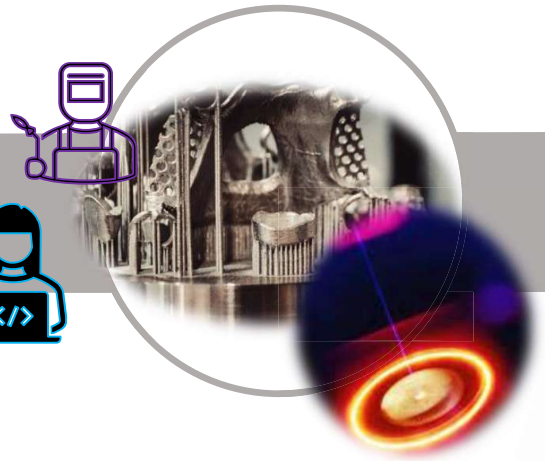

DICOM and Meta Data
OR
MDM
Data Transfer
PACS Server
Storing and retrieving images
PACS
Radiologist
Analysis and data release
from Product X into EMR
by Radiologist
DICOM
Protocol
DICOM
CT
Modality
Product X
PACS Server
DICOM
Viewer
EHR/
EMR
HL7 OBX CT
Files
Link to
Product X
PDF Report
DICOM
Selected Medical
Records
Radiologist
Patient
RIS:
Administration
Demand Planning
Accessioning
RIS
Radiologist
MDM
Designer
Raw
DICOM
Raw
STL
Final
3D CAD STL
Segmentation
Design
Design for Physician Approval
Final Design and Surgical
Technique
Physician
Consultation
ICF Approval
OR
Patient
PACS: Picture Archiving and Communication System
RIS: Radiology Information System



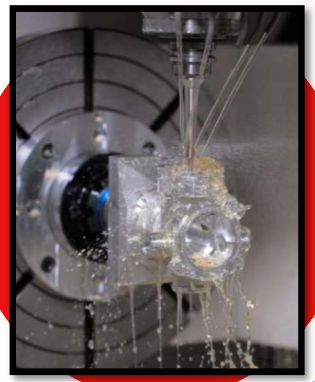
Design to Machine File(s) Conversion

&

Manufacturing Feasibility



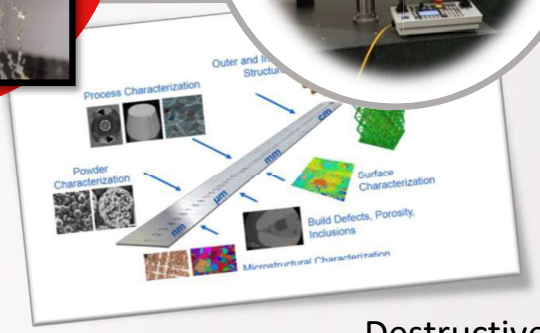
3DP Build(s)



Post Processing

QC

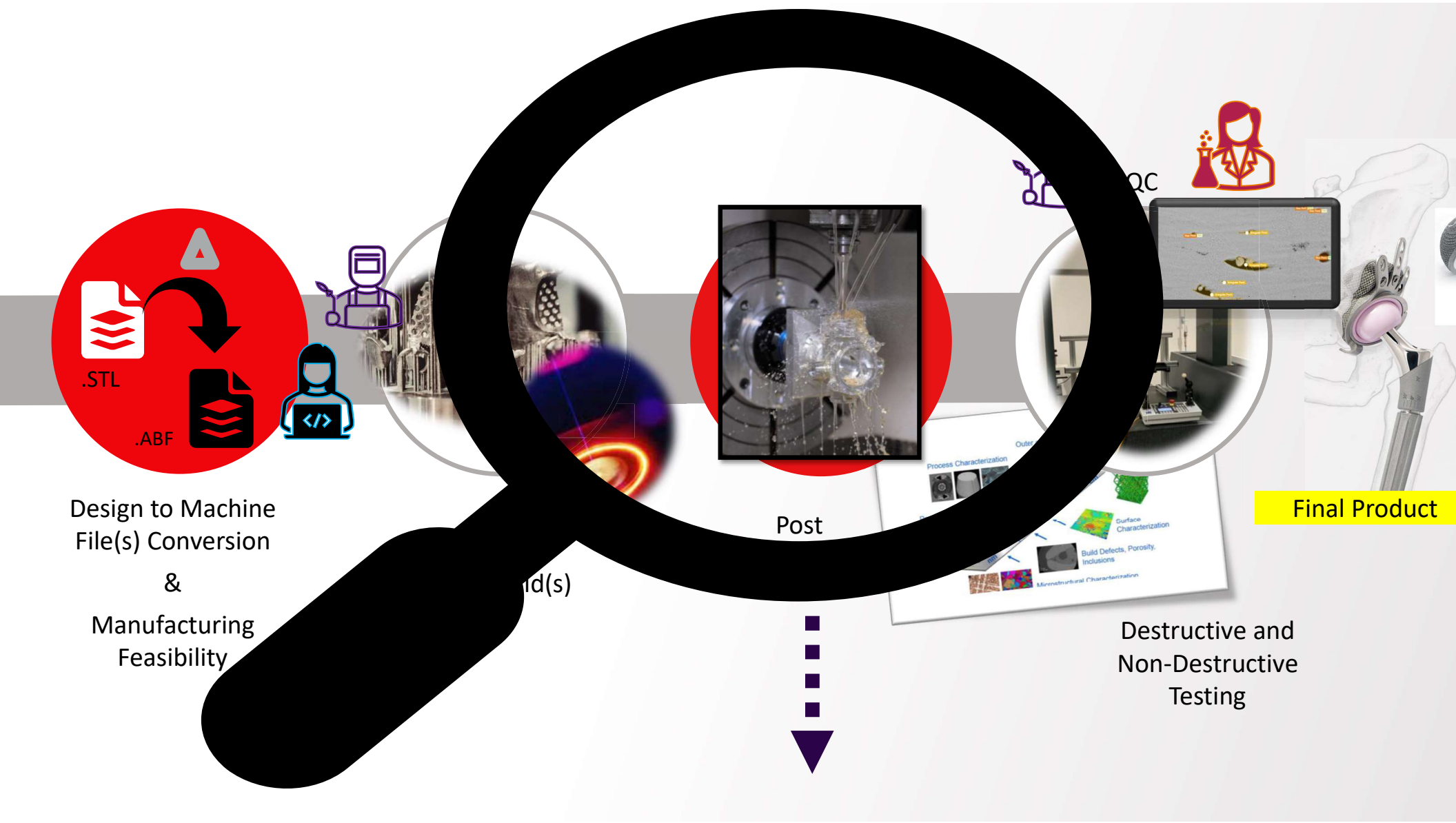


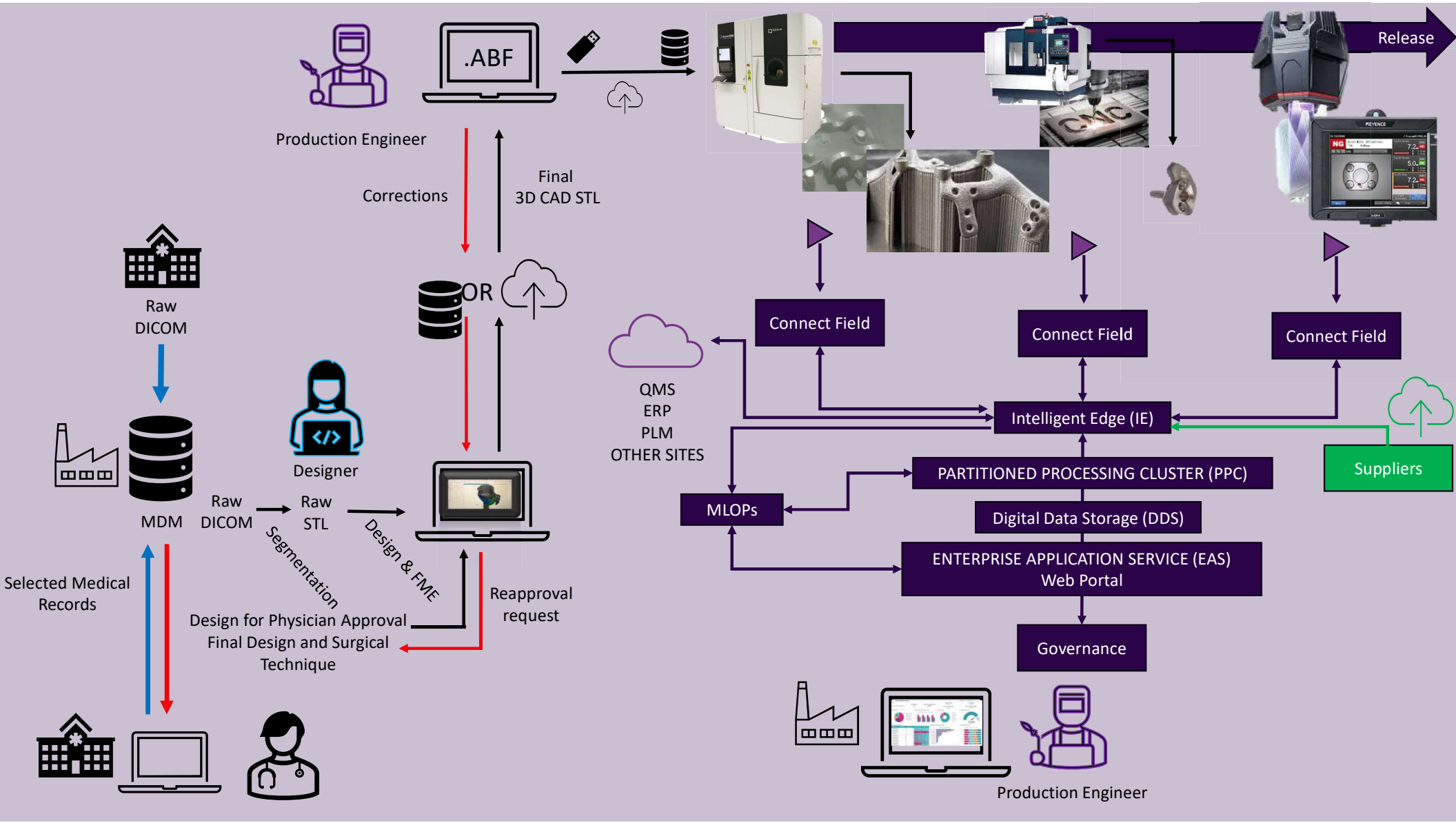


Destructive and Non-Destructive Testing



Final Product


.STL
.ABF
Design to Machine File(s) Conversion
&
Manufacturing Feasibility
Post
QC
Destructive and Non-Destructive Testing
Final Product


.ABF
Production Engineer
Corrections
Final
3D CAD STL
Release
Raw
DICOM
OR
Connect Field
Connect Field
Connect Field
QMS
ERP
PLM
OTHER SITES
Intelligent Edge (IE)
Designer
MDM
Raw
DICOM
Raw
STL
Segmentation
Design & FME
Suppliers
PARTITIONED PROCESSING CLUSTER (PPC)
MLOPs
Digital Data Storage (DDS)
ENTERPRISE APPLICATION SERVICE (EAS)
Web Portal
Selected Medical
Records
Reapproval
request
Design for Physician Approval
Final Design and Surgical
Technique
Governance
Production Engineer

Not MDPS, Yet


Northwell Health


RICOH 3D for Healthcare


HSS
Lima Corporate
Orthopaedic motion

Future Turn-Key MDPS Goal



HDO/ MDM Data Sharing

HDO/ MDM Data Sharing

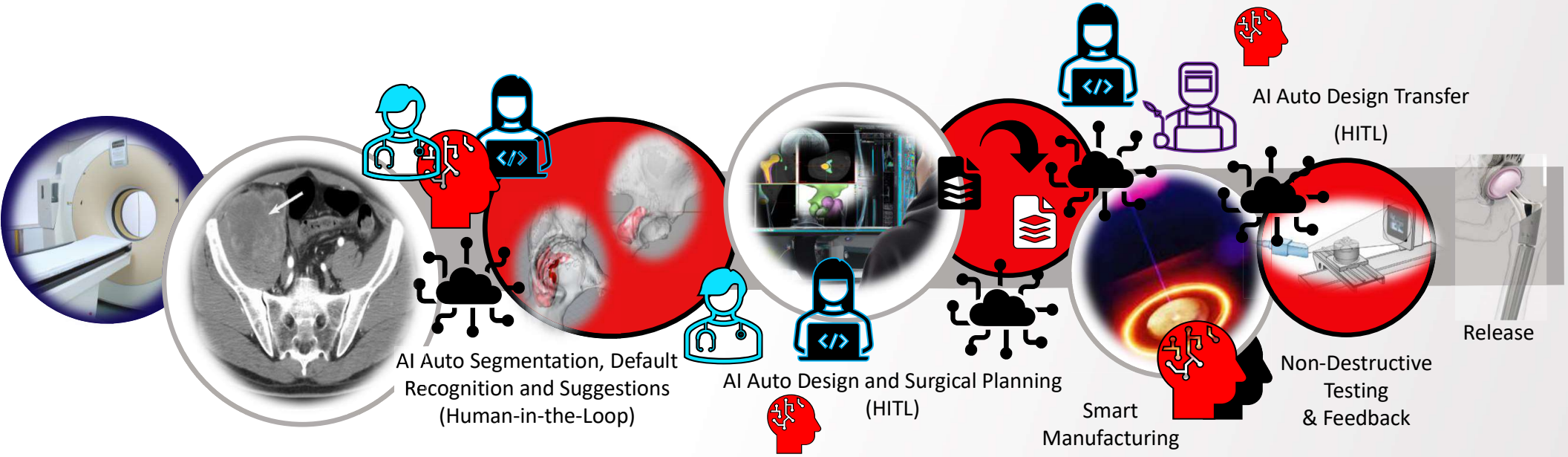
HDO/ MDM Data Sharing

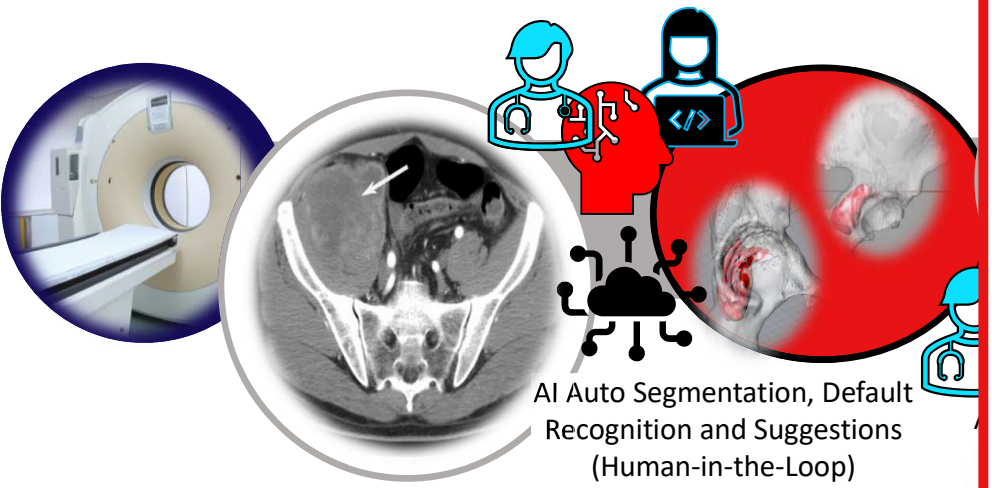
MDM = Medical Device Manufacturer
HDO = Health Delivery Organization

AI Enabling Will Foster Real MDPS



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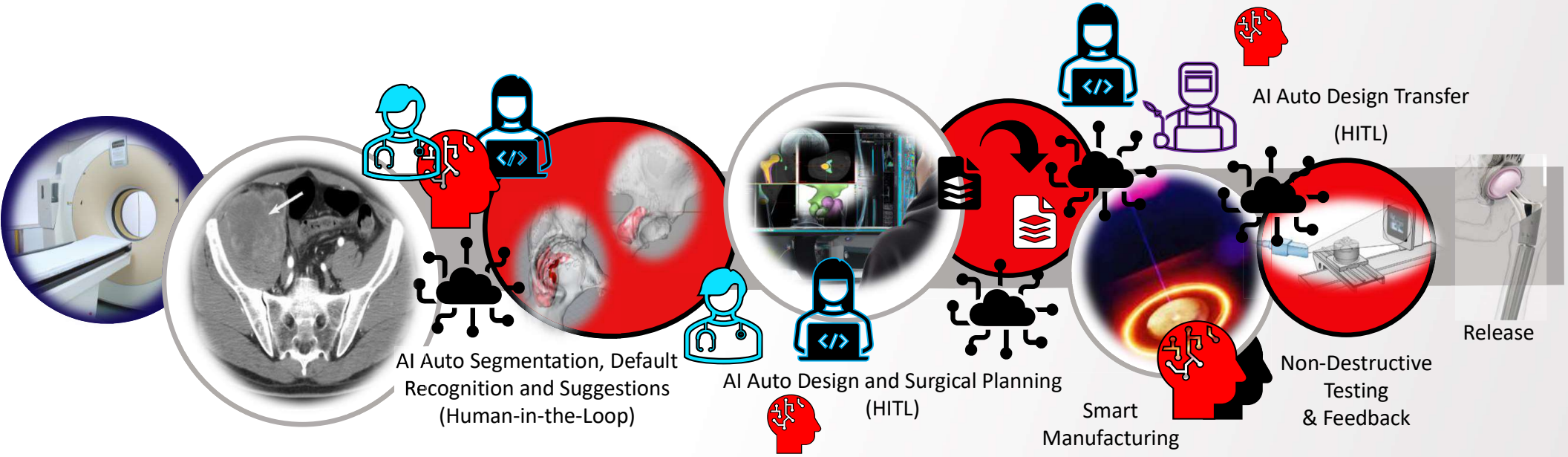

AI Auto Segmentation, Default Recognition and Suggestions (Human-in-the-Loop)
AI Auto Design and Surgical Planning (HITL)
AI Auto Design Transfer (HITL)
Smart Manufacturing
Non-Destructive Testing & Feedback
Release

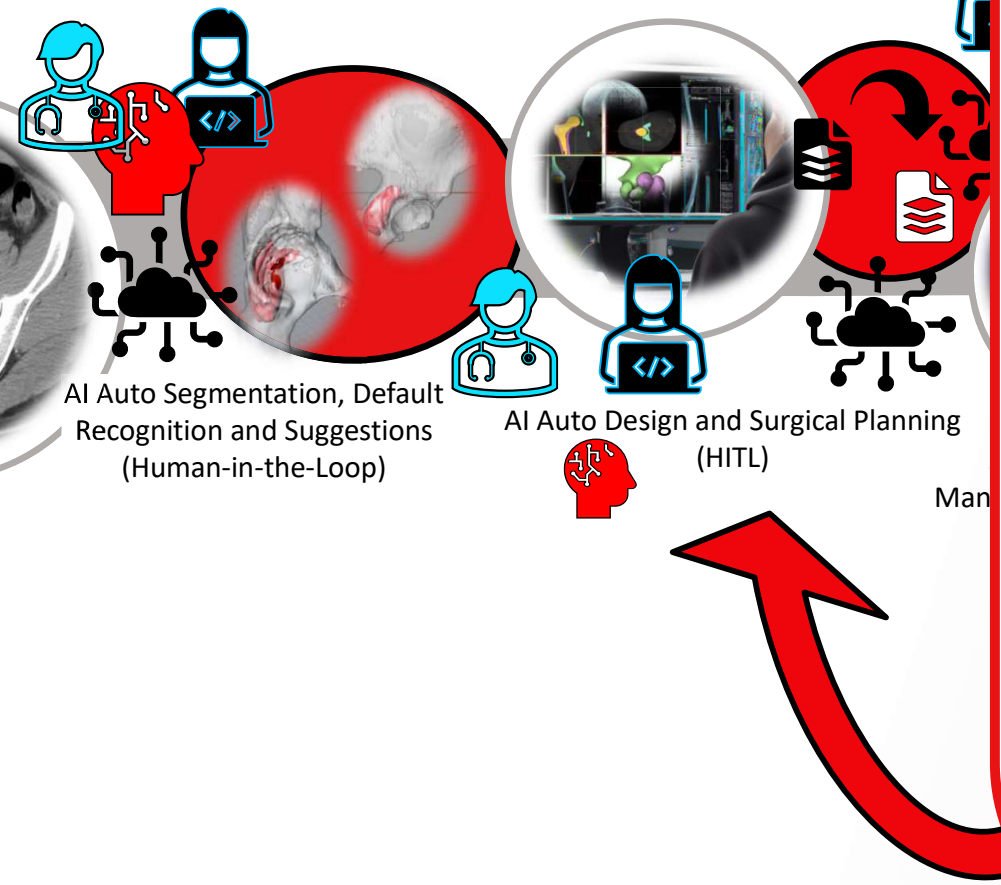


AI Auto Segmentation, Default Recognition and Suggestions (Human-in-the-Loop)

AI Enabled Segmentation

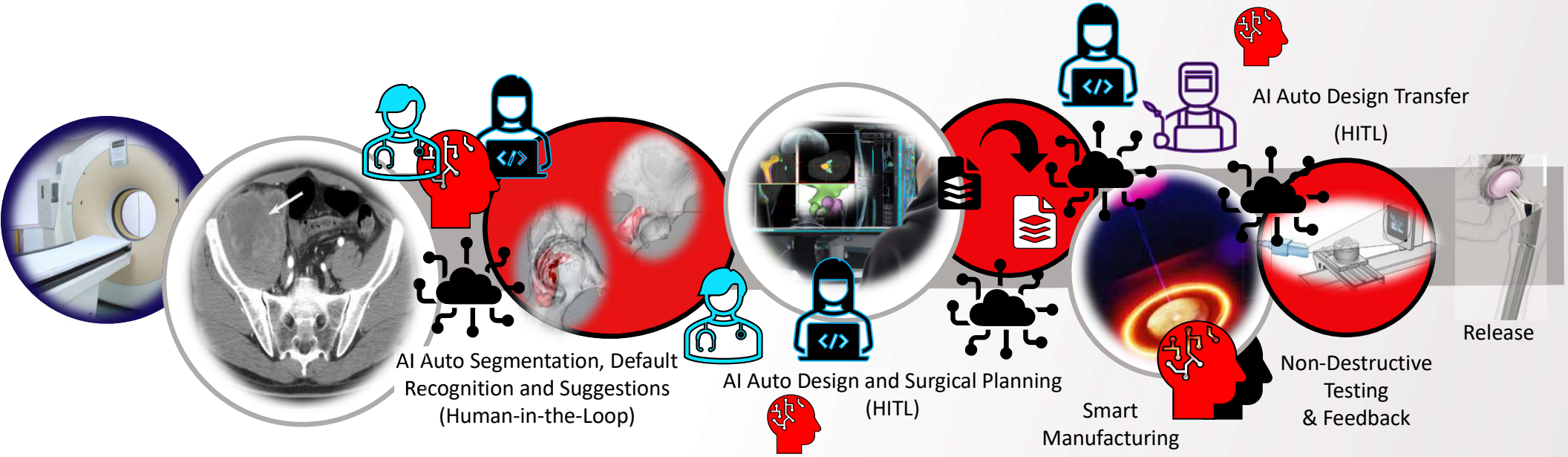
- HITL verification from Radiologists and Surgeon
- Takes 2D image “slices” and combines them to a 3D image
- Identifies defect regions of interest with colored masks

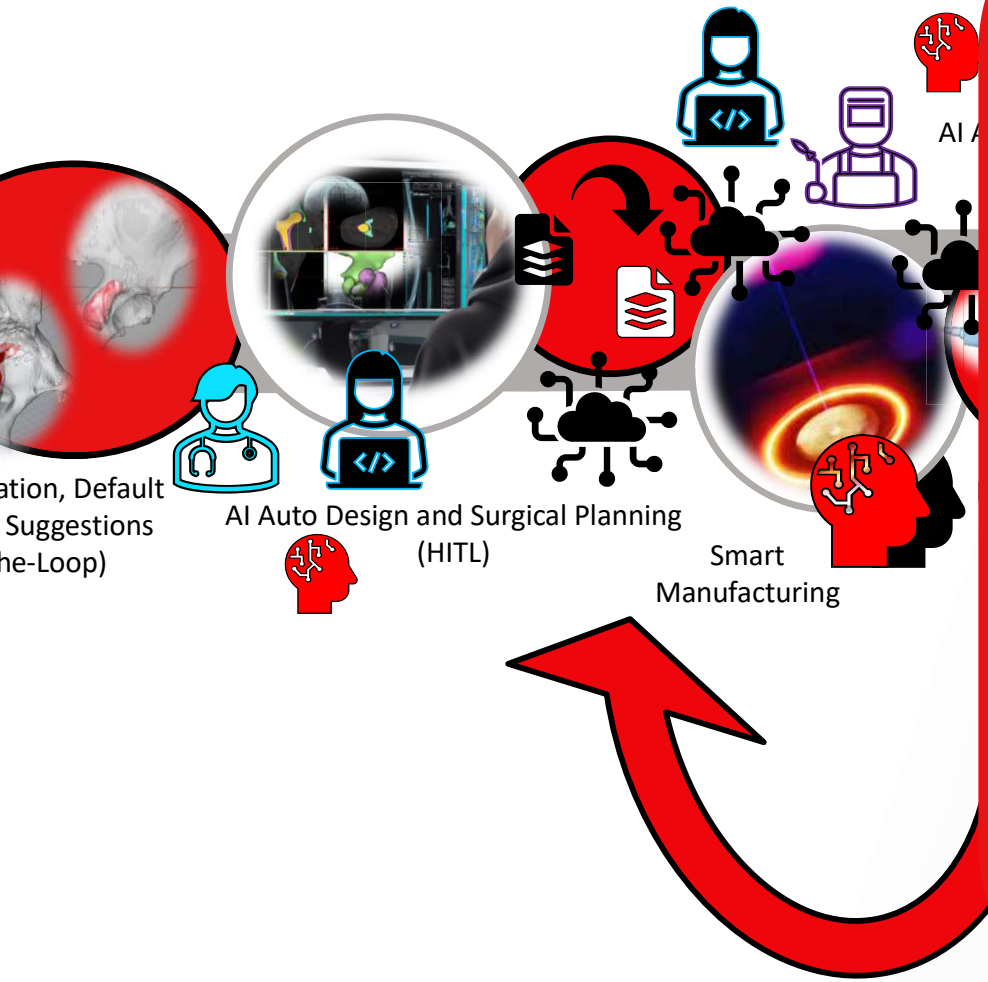

AI Auto Segmentation, Default Recognition and Suggestions (Human-in-the-Loop)
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Release



AI Enabled Design

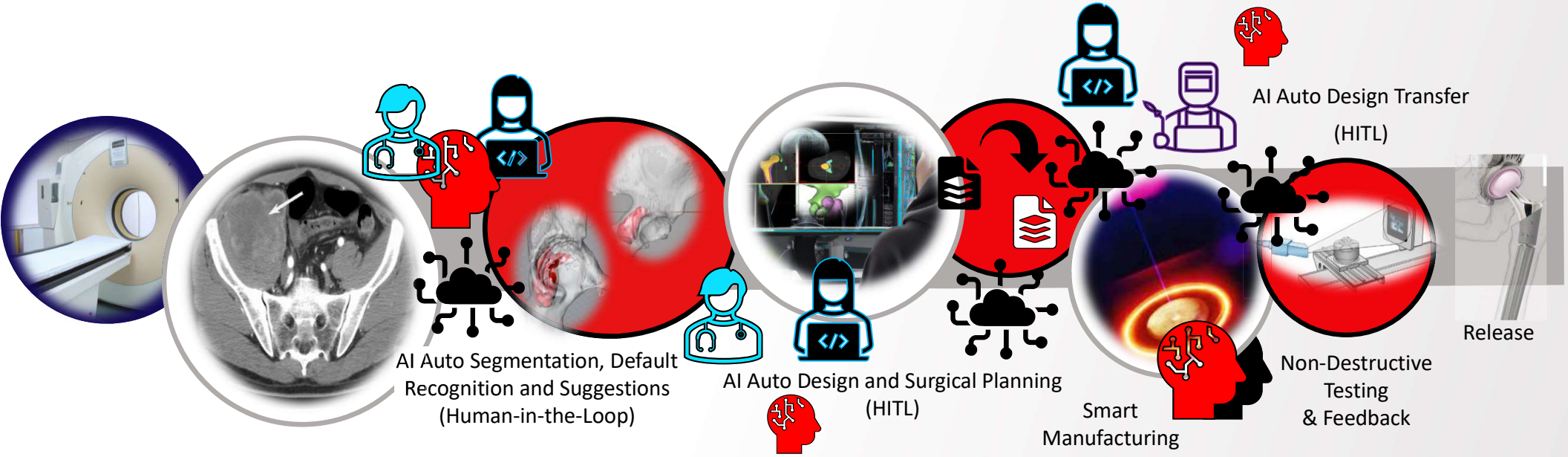
- With HCPs and validated/ released by Engineers:
  - Identify and suggest defect and defect solution
  - Build surgical technique, including bone reduction
  - Build implant based on technique, defect need (in the future, includes patient genetic considerations), and regulatory guardrails
- Predictive surgical outcomes reported.
- Designs with poor build outcomes will not be allowed.
- API Connection to Nonconformity Report (NCR) system and complaint system.

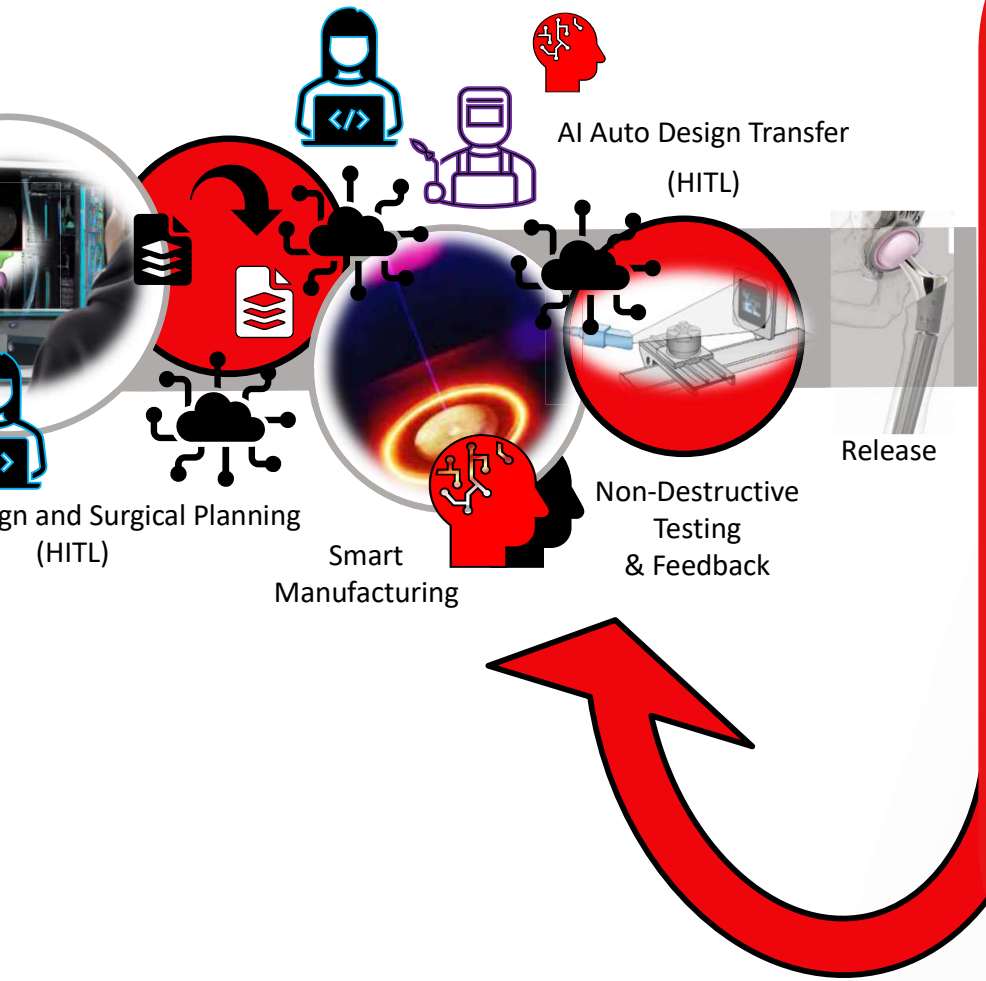

AI Auto Segmentation, Default Recognition and Suggestions (Human-in-the-Loop)
AI Auto Design and Surgical Planning (HITL)
AI Auto Design Transfer (HITL)
Smart Manufacturing
Non-Destructive Testing & Feedback
Release



AI Enabled Design Transfer

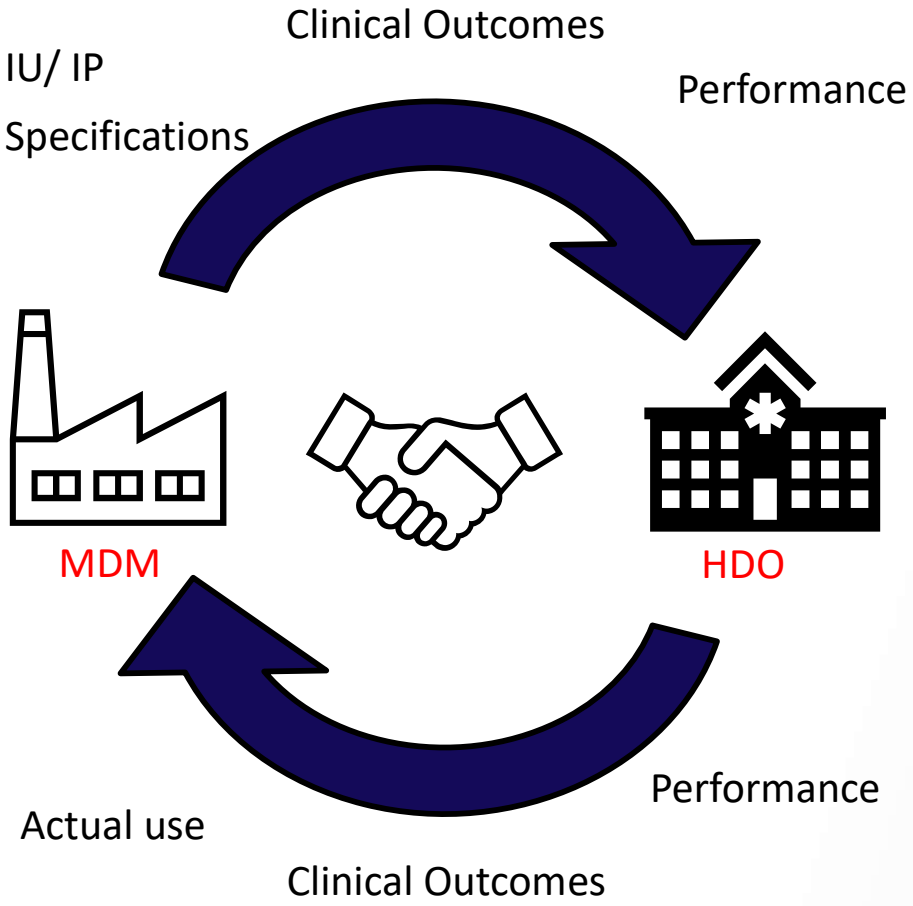
- With validated process and data, automatically:
  - Convert design file to machine file.
  - Determine build feasibility and build bed/ zone location.
  - Material concerns from supplier/ incoming inspection data.
- Predictive outcomes reported and design rework process avoided.
- API Connection to NCR system and complaint system.


AI Auto Segmentation, Default Recognition and Suggestions (Human-in-the-Loop)
AI Auto Design and Surgical Planning (HITL)
AI Auto Design Transfer (HITL)
Smart Manufacturing
Non-Destructive Testing & Feedback
Release

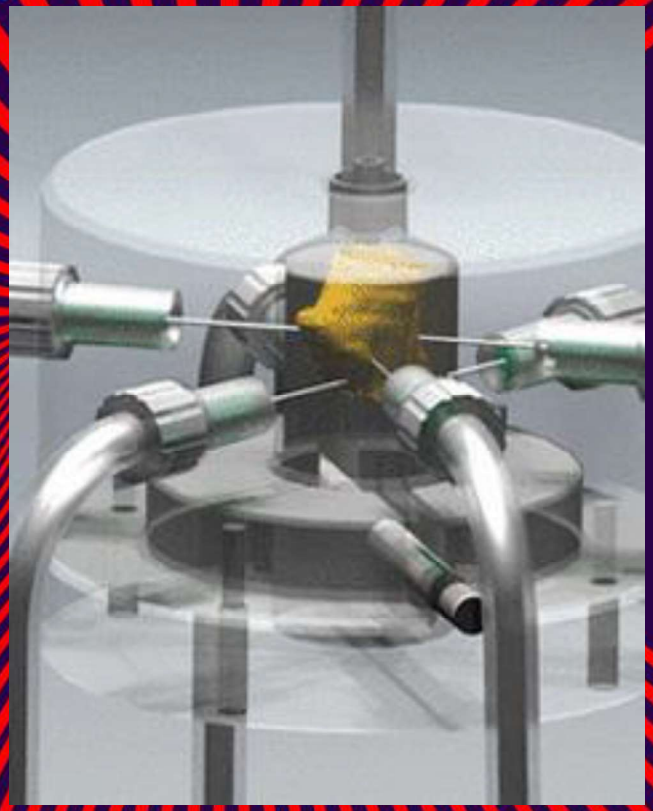


AI Enabled Manufacturing

- With validated process and data, automatically:
  - Convert design file to machine file.
  - Determine build feasibility and build bed/ zone location.
  - Material concerns from supplier/ incoming inspection data.
- Predictive outcomes reported and design rework process avoided.
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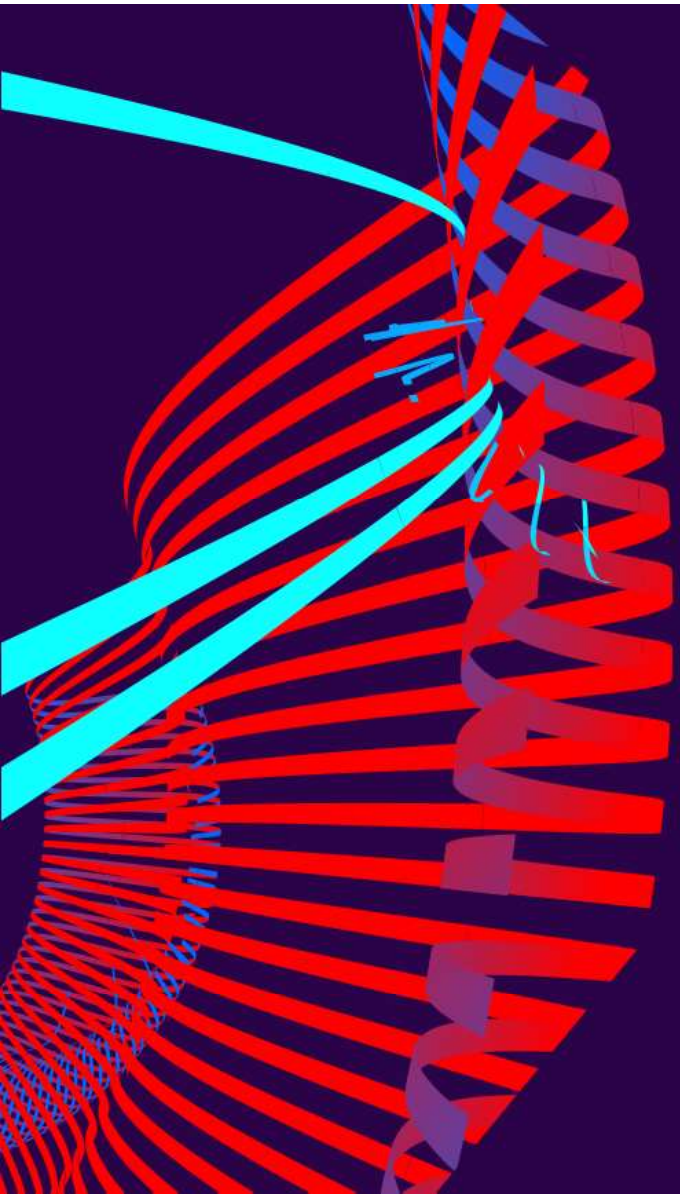


- Data sharing agreements and platforms:
  - Meet HIPAA, HL7, and global requirements
    - Privacy, Security, Ethics
  - Support patient specific care
  - Support post market surveillance and design
  - Leverage hospital automation
  - Anticipate unintended use
  - Better understand voice of customer
- MDM provided certified training
  - For end users
  - For hospital engineering/ internal maintenance groups and/ or Independent Service Organizations (ISOs)
  - Educate risk concerns of knock offs



NEXT GEN HUMANITY IS CLOSE

https://pages.jh.edu/graysonlab/research.html



WE ARE IN A DEUS EX HUMAN MOMENT...