HCL

Engineering partnership towards patient centric ecosystem

Acceleration | Compliance | Value

Sustenance engineering service
by HCL

HCL has co-created 170+ Medical and IVD devices. 85% of the resources work in sustaining legacy products for 9/10 Medical Device firms. Leverage our expertise in product feature changes, component engineering, product lifecycle engineering and adverse event management, to increase product life and revenue with higher customer retention.

HCL's Commercial Product Engineering Capability

Design Change Management

ECN / DCN Handling   **Documentation**   **PLM / PDM Support**

Change Request Creation (left side vertical label)

Change Request Implementation (right side vertical label)

Design to Cost (DTC)	Regulatory and Compliance	Adverse Event Management	Component Engineering	Product Lifecycle Engineering	Product feature changes
• Tear Down Analysis • Benchmarking • Cost Modeling and Should Costing • Functional Analysis • Cost to Function Analysis • Feature EnhancementsTest Automation • Remodel server infrastructure • Improve preventive maintenance in software • Enable Data analytics to reduce field visits by service person and device downtime	• DHF Remediation • Product Re-certifications • Product Localizations • New Regulation Adherence • Enable Cybersecurity • Software updates for new Regulation adherence • SW enhancement – 62304 compliance for alarm standards	• Field failure analysis & CAPA • Design Analysis • Design Support • Documentation • Test Method Development and Validation • Defect Fixes / Bug Fixes - (L2/ L3 support for issue analysis)	• Technology changes • PCN / EOL review and support • Raw Material Changes • Tin Whisker Study & Mitigation in Component Level • Identification of Alternate Components / Vendors • Performance Improvement • Code refactoring	• Manufacturing Issue resolution • DFM Study • Engineering Change Management • Root Cause Analysis • Risk Management • Reliability Engineering • Manufacturing test Software • EOL programming • IQ/OQ/PQ • SW porting / Migration • DevOps Implementation Support – TFS, GIT	• Feature Enhancements • GUI Localization (multilingual support) • Field issues management for Software • Enable connectivity • Software Change Support for Electrical Obsolescence • Impact Analysis - UI Changes

Program Management

Risk Management   **Communication Management**   **Stakeholder Management**   **Knowledge Management**

Owning Sustenance Engineering – Why HCL?

HCL Enablers

Functional Expertise
- Cross leverage experience across carrying similar projects across multiple industries

Frameworks & Accelerators
- Proprietary modular, scalable, and highly customizable framework for verification and testing

Complete Ownership of Sustenance
- Demonstrable experience in ownership of product lines for leading MD customers

Resources with Knowledge of "Client" Processes
- Skilled Resources with Medical Device, Client Product & Process knowledge

HCL's Centers of Excellence (CoE)
- Leverage HCL's CoEs in H/W, RF, Mech., Regulatory etc. for best practices and faster implementation

Infrastructure
- Significant investment in in-house engineering labs, and tools

Value Delivered to "Client"

Predictability of Results
- Prior knowledge of expected business results and related cost. Monitor performance through SLAs

Focus on Innovation
- "Client" frees bandwidth for their engineers. Engage them in more innovative & critical projects

Improved Knowledge Management
- Leverage HCL's pool of resources dedicated for "client" across multiple OpCos

Bring Flexibility
- HCL owns the responsibility for quick ramp-up/down with minimal impact on project & knowledge

Better Risk Mitigation
- Attrition, timeline, effort, outcome related risks are transferred from "client" to HCL
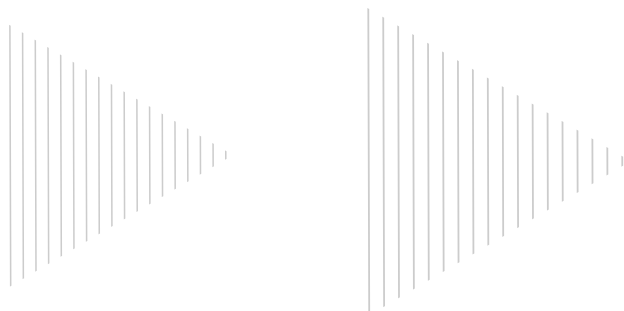
Lower Total Cost of Ownership for "client"
- Cost advantage for "client". Utilize HCL's onsite-offshore model to provide YoY benefits in cost

De-risk Transition with Proven Approach
- Track progress of sustenance ownership across phases of transition with proven metric systems & SLAs

HCL's Sustenance Engineering Credentials

Overall Experience

- 15+ years of after market support expertise
- 8+ leading Medical Devices OEM's extensively supported for sustenance
- 3000+ resources dedicated for Medical Devices Sustenance
- Over 85% of HCL Medical Devices Revenue from Sustenance

Experience with Cross Functional Teams

- Demonstrable experience of working across Product Development, QRC and Operations teams
- Mechanical Center of Excellence
- Regulatory and Clinical Center of Excellence
- Hi-SCORE – VAVE, Cost Modelling, FEA
- STRIDE – Strategic Research, Innovation and Design for Experience
- VLSI
- Product Testing Services (PTS)

Device Classification

- Class I, II & III

HCL Sustenance Experience

Solutions and Frameworks

- ATLAS, iSE, eDAT, TAF – to accelerate the change implementation, automation
- CARE Platform – Connected Assets in Regulated Environment

Device Categories

Domain experts across the following therapeutic areas:

- Capital Equipment
- Diagnostic Devices
- Implantable Devices
- Remote Patient Monitoring Systems
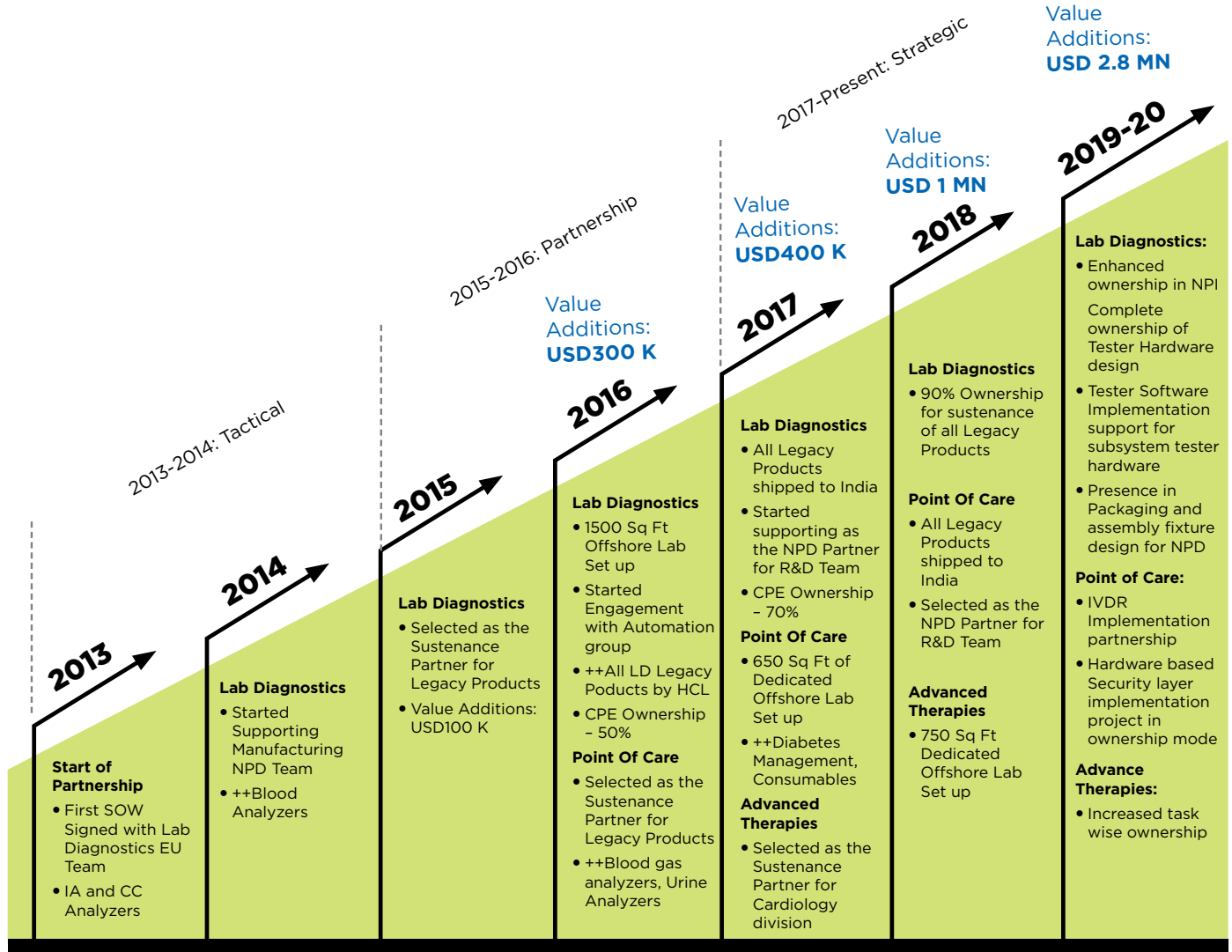- Consumables and Reagents

Product Management Areas

- Patients Safety and Quality Improvement
- Regulatory and Compliance
- Cost Improvement Programs
- Operations support

HCL's Sustenance journey with a leading European based MedTech company

2013

Start of Partnership
- First SOW Signed with Lab Diagnostics EU Team
- IA and CC Analyzers

2014

Lab Diagnostics
- Started Supporting Manufacturing NPD Team
- ++Blood Analyzers

2015

Lab Diagnostics
- Selected as the Sustenance Partner for Legacy Products
- Value Additions: USD100 K

2016

Value Additions: **USD300 K**

Lab Diagnostics
- 1500 Sq Ft Offshore Lab Set up
- Started Engagement with Automation group
- ++All LD Legacy Poducts by HCL
- CPE Ownership – 50%

Point Of Care
- Selected as the Sustenance Partner for Legacy Products
- ++Blood gas analyzers, Urine Analyzers

2017

Value Additions: **USD400 K**

Lab Diagnostics
- All Legacy Products shipped to India
- Started supporting as the NPD Partner for R&D Team
- CPE Ownership – 70%

Point Of Care
- 650 Sq Ft of Dedicated Offshore Lab Set up
- ++Diabetes Management, Consumables

Advanced Therapies
- Selected as the Sustenance Partner for Cardiology division

2018

Value Additions: **USD 1 MN**

Lab Diagnostics
- 90% Ownership for sustenance of all Legacy Products

Point Of Care
- All Legacy Products shipped to India
- Selected as the NPD Partner for R&D Team

Advanced Therapies
- 750 Sq Ft Dedicated Offshore Lab Set up

2019-20

Value Additions: **USD 2.8 MN**

Lab Diagnostics:
- Enhanced ownership in NPI
- Complete ownership of Tester Hardware design
- Tester Software Implementation support for subsystem tester hardware
- Presence in Packaging and assembly fixture design for NPD

Point of Care:
- IVDR Implementation partnership
- Hardware based Security layer implementation project in ownership mode

Advance Therapies:
- Increased task wise ownership

Sustenance Engagement with LD division of a leading European based MedTech company

Challenges

Customer's LD division had a very urgent need to complete RoHS compliance for one of their complex integrated chemistry products and was looking for a strategic partner who has extensive product sustenance experience to take up sustenance ownership of legacy **medical devices** to enable Customer's workforce to focus on next generation product.

HCL Solution

HCL did excellent job in the pilot project by taking complete ownership of part **RoHS compliance.** This was done with offshore onsite model of well trained resource and brilliant project planning to handle multiple activities in parallel to meet the aggressive schedule target. The customer's was able to get the RoHS compliance on time though this project started just few months before the deadline for compliance.

By seeing the good performance of pilot project, Customer's approached HCL for its legacy product sustenance program. HCL prepared a detailed , step by step strategy to transfer the complete sustenance ownership to HCL over a period of 5 years.

HCL established lab infrastructure, secured Customer's Offshore development center, Customer's network connectivity infrastructure inside ODC at HCL India premises. An extensive product training plan including product service training , step by step Knowledge transfer plan with competency maturity model mapping to customer's competency levels helped to expedite the work transfer from customer'sto HCL. Within the duration of 3 years, HCL could own 85% of sustenance engineering activities successfully and can handle all critical verification activities at HCL India Lab for all legacy LD instruments. HCL could complete more than 800 engineering changes successfully and can provide solutions for part obsolescence, CAPA activities, manufacturing & service issue, risk remediation, part cost reduction, field complaints, complex design changes, regulatory and labeling related changes.
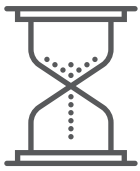
Value Delivered

- Successful completion of **RoHS compliance** project on time which enabled customer's to continue their one of the important LD products sales at EU & US

- 800+ engineering changes

- USD 500,000 worth value delivered by process cost reduction and product cost reduction projects

- Around USD 1 Million annually cost saved due to HCL's offshore – onsite model of business

- The customer could move all their engineering expert team to the new product development activities relieving them from legacy sustenance activities

CASE STUDY:
One of the Top 10 MedDevice Manufacturers

A healthcare company with primary focus on products to treat hemophilia, kidney disease, immune disorders and other chronic and acute medical conditions
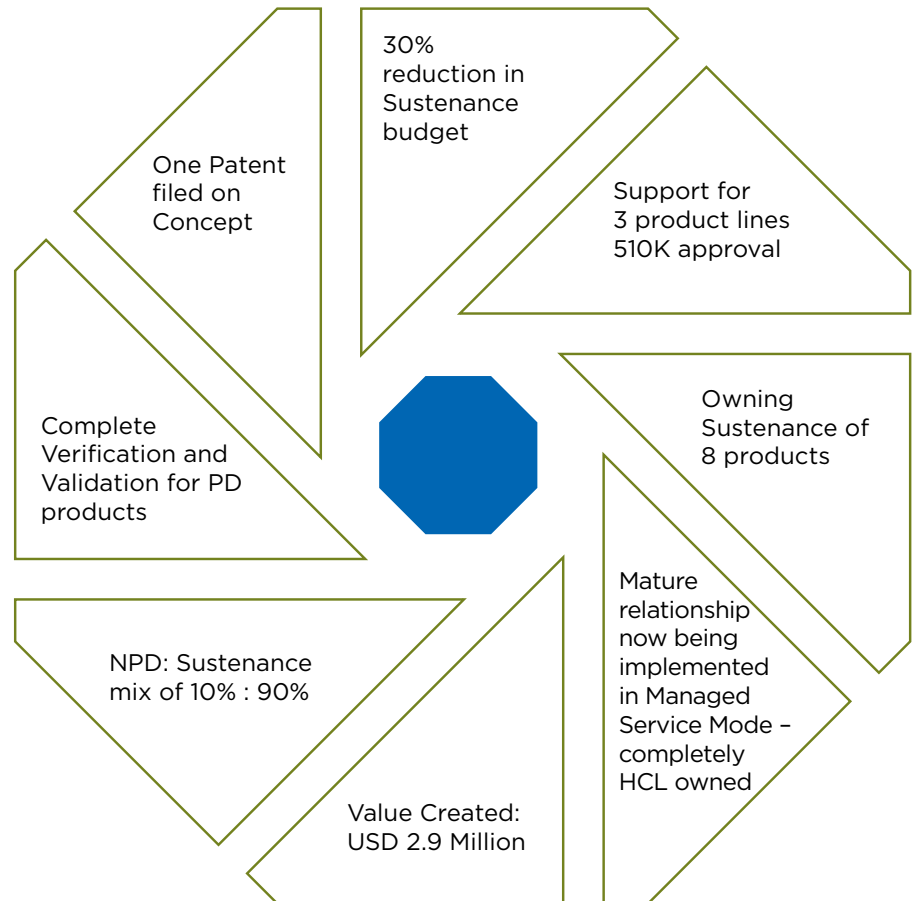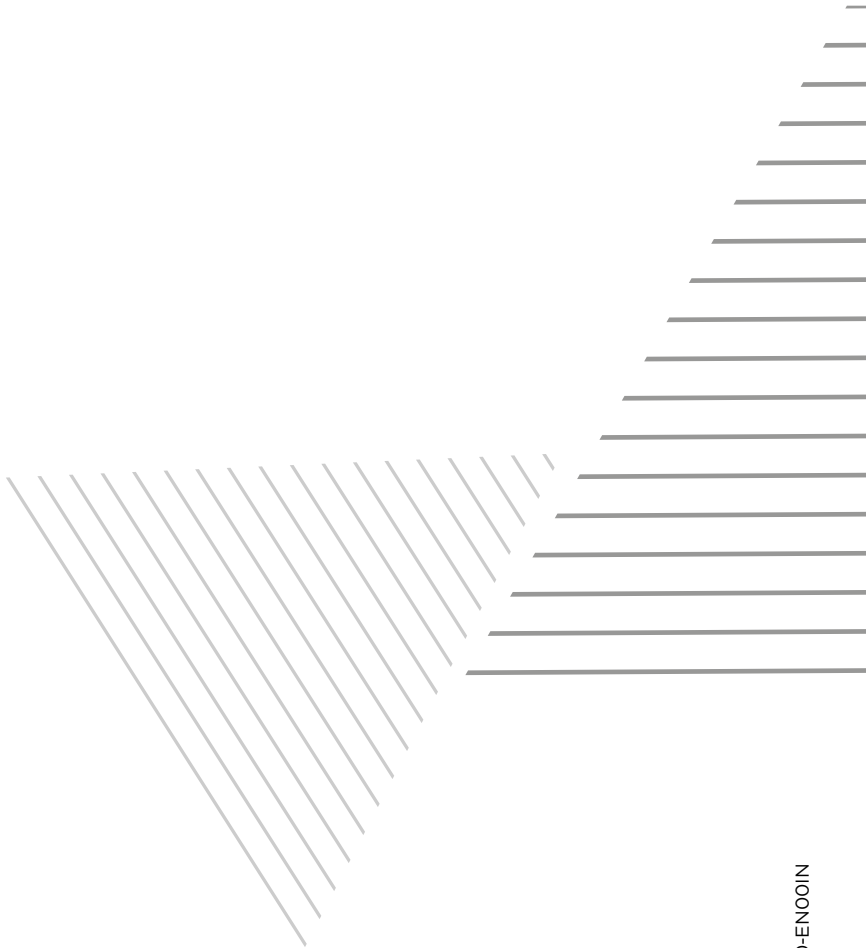
14+
Years Relationship

800+
HCL Engineers

One Patent filed on Concept

30% reduction in Sustenance budget

Support for 3 product lines 510K approval

Complete Verification and Validation for PD products

Owning Sustenance of 8 products

NPD: Sustenance mix of 10% : 90%

Mature relationship now being implemented in Managed Service Mode – completely HCL owned

Value Created: USD 2.9 Million

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