

# UVA10a/b/c

## UPGRADE VALIDATION ASSISTANCE SERVICES



NOTOCORD-hem™ versions

Upgrading and validating a software version in a GLP environment is usually time-consuming and costly, requiring both human and material resources. Among the consequences, customers often wait a long time to benefit from software corrections and new features.

NOTOCORD® **Upgrade Validation Assistance** (UVA) is a service designed to **speed-up** and increase the efficiency of the upgrade process of NOTOCORD-hem™ software in a customer's **GLP** regulated environment. Its flexible and **customized methodology** is based on **risk analysis** and adapted to the customer's experimental protocols and needs.

Our target time for the upgrade validation is **1 to 3 months**.

## A 3-LEVEL OFFER

The UVA service is provided as a 3-level package:

UVA10a	<b>Impact analysis</b> Evaluation of software changes
UVA10b	<b>Test script design + UVA10a</b> Preparation of validation documents
UVA10c	<b>Testing activities + UVA10b</b> Installation, tests execution, reporting

## KEY FEATURES

- Reduced delay and cost of upgrade process
- Active collaboration between users, IT, QA and NOTOCORD® teams
- Methodology focused on key topics
- Risk-based analysis approach
- Customization for the customer's protocols
- NOTOCORD® QA tests provided as tests statements
- Tests execution with NOTOCORD® assistance
- Software upgrades available immediately

## OUR EXPERTISE ON OUR PRODUCTS

No heavy books are required with UVA. Our approach is based on risk analysis and **focused on critical points**. Because we are expert on the system we develop and support, we can advise you wisely on operating the software.

The service is customizable to answer customer's requirements and specific procedures. NOTOCORD® proposes a general methodology adapted to your **Change Control** procedure, and provides **tests statements** adapted to your protocols.

From the **experience** we gained with several laboratories working in GLP environment, we truly understand what is needed to decrease your own workload in relation to validation purposes, and to keep disruptions at a minimum. Our teams actively collaborate with you throughout the validation project, **reducing delay** and therefore the overall **cost** of the upgrade process!

# BACKBONE OF THE UVA SERVICE WITH DELIVERABLES AND SERVICE ACTIVITIES

## UVA10a/b/c

### Project preparation



Responsibilities  
Scope  
Prerequisites

**Impact analysis**  
Software changes evaluation



Recommendations  
Software upgrade risk analysis

**Test scripts design**



NOTOCORD® QA Tests Statements  
IQ document preparation  
OQ / PQ tests scripts

**Upgrade installation**



NOTOCORD® expert on site  
IQ document completion

**Test execution**



Test results (OQ / PQ)  
Protocol deviation log  
Reference data file & spreadsheet

### Final review & approval

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## THEY TRUST NOTOCORD

*"We upgraded from NOTOCORD-hem 4.2 (working on XP) to 4.3 (working on W7) for an Isolated Heart system. NOTOCORD adapted its methodology to our different needs. The impact analysis has been very helpful in the validation process. Definitions were very clear and we much appreciated the level of details provided in the documents. A specialized and dedicated contact helped us focus on the most critical points needed for the next steps. Thanks to the NOTOCORD Upgrade Validation Assistance service, we saved precious time."*

**Liomar Neves, Ph.D., Senior Scientist at CorDynamics, Inc.**



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Speeding up Research, Empowering Science™