

# **Advanced Biological Laboratories Receives CE Registration for its NADIS ® Software, a Specialty Patient Management System Dedicated to the Management of Patients Suffering from Chronic Infectious Diseases**



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Advanced Biological Laboratories (ABL) and Fédialis Médica announced today the CE registration of its NADIS® Software which is a specialty patient management system tailored for infectious diseases to diagnose disease staging, to monitor patients' infection levels and to support prescription antiviral / antimicrobial therapies in conjunction with other drugs and clinical conditions (underlying and past).

The NADIS® Software is a standalone medical device intended to be used for the purpose of prevention, monitoring, treatment or alleviation of a chronic infection disease such as HIV, HCV, HBV.

Currently installed in more than 192 public hospitals (CH / CHU) in France and 28 hospitals in Africa, this robust clinical software handles the transversal management of chronic diseases and can be used by multiple stakeholders involved in the collection of medical data to optimize quality of patient care overall.

The system is a secured client-server application designed by a network of infectious diseases experts (clinicians, virologists...)

which can be made available through Cloud access (including server hosted within Data Healthcare Compliant environments – HDS) or through local appliances. It includes a common core application (demographics, clinical conditions, treatments history...) as well as several specialized modules tailored to HIV / Hepatitis patients, rare diseases (Ex.: Lupus) and pneumology. All patient files include a monitoring and evaluation module for therapeutic education programs.

The collected information is then used as inputs to offer to prescribers support for determining a drug prescription, to improve the safety of prescription, facilitate the work of the prescriber, encourage conformity of the prescription with national regulatory requirements and reduce the cost of treatment at the same quality.

The NADIS® Software is also collecting and exchanging drug history, lab test results, clinical information with third party software to evaluate drug resistance of combination therapies for HIV, HCV, CMV and vaccine-escape for HBV infected patients.

“Obtaining CE registration of our NADIS® Software is a great asset for clinicians requiring efficient tools for optimizing the management of chronic diseases overall and patient care.” said Dr. Chalom Sayada, CEO of ABL.

“We have consolidated Nadis and adapted it in particular to the follow-up of patients in the information, screening and diagnostic centers (CeGIDD) with the addition of new functionalities such as the MyNadis™ module, the eVisit module™ and the remote eMonitoring™ module”, adds Mr. Mohammed Errafyqy, customer relations manager at ABL France.

“We have engaged tremendous efforts to standardize the entire line of solutions of the company including specialty patient management systems like NADIS® as well as our diagnostics line of molecular biology assays and software. We are aiming to standardize all relevant IT solutions in the context of the transition from the European Directives for medical devices (93/42/EEC and 98/79/EC MDD and IVDD) to the European Regulations (2017/745 and 2017/746)” explained Mr. Ronan Boulmé, GRC Director at ABL.

To learn more about NADIS® Software please visit

Advanced Biological Laboratories (ABL), S.A., is a diagnostic and medical software company founded in 2000 as a spin-off from CRP-Santé (<https://www.lih.lu/>) Luxembourg.

ABL took in 2013 the rights to all viral hepatitis B & C related assets from EVIVAR MEDICAL as well as a personalized medicine electronic medical record system (EMR) in infectious disease from GlaxoSmithKline in 2016. In July 2018, acquired CDL Pharma to develop CRO related services and assays manufacturing capacity. In June 2019, ABL created its affiliate in the USA (AdvancedDx Biological Laboratories) covering the entire North American territory.

ABL has a comprehensive suite of healthcare management products, including Nadis®, TherapyEdge®, ViroScore®, SeqHepB, DeepChek®, UltraGene®, VisibleChek®, HepatiC®, BacterioChek, MicrobioChek and the DPM used for data and patient management, monitoring and personalized reporting applications. Since 2012, some of ABL's products are CE-IVD marked. In 2020, ABL got CE-IVD marking for its DeepChek®-HIV and DeepChek® Whole Genome SARS-CoV-2 Genotyping assays as well as for its UltraGene Combo2Screen SARS-CoV-2 assay and for its UltraGene SARS-CoV-2 Multi Variants Deletions V1 assay and Triplex assay. The other products are currently available for Research Use Only. Please consult ABL team for further information about registration status of the ABI's products in your territory.

Actuellement installé dans plus de 192 hôpitaux publics (CH/CHU) en France, et 28 centres en Afrique, ce logiciel clinique robuste gère la gestion transversale des maladies chroniques et peut être utilisé par de multiples acteurs impliqués dans la collecte de données médicales pour optimiser la qualité de la prise en charge globale des patients.

Le système est une application sécurisée conçue par un réseau d'experts (cliniciens, virologues...) qui peut être mis à disposition dans des environnements d'Hébergement de Données de Santé - HDS) ou via des installations locales. Il comprend un tronc commun d'applications (démographie, conditions cliniques, historique des traitements...) ainsi que plusieurs modules spécialisés adaptés aux patients

VIH/hépatite, maladies rares (Ex. : Lupus) et pneumologie. Tous les dossiers patients comprennent un module de suivi et d'évaluation des programmes d'éducation thérapeutique.

« Nous avons consolidé Nadis ces dernières années et l'avons adapté notamment au suivi des patients dans les centres gratuits d'information, de dépistage et de diagnostic (CeGIDD) avec l'ajout de nouvelles fonctionnalités comme le module MyNadis™, le module eVisit™ et celui de remote eMonitoring™ », ajoute Mr. Mohammed Errafyqy, responsable relations clients chez ABL France.

« Nous avons déployé des efforts considérables pour standardiser l'ensemble de la gamme de solutions de la société, y compris les systèmes de dossiers médicaux électroniques comme NADIS® ainsi que notre gamme diagnostic de tests et de logiciels de biologie moléculaire. Nous visons à standardiser toutes les solutions pertinentes dans le contexte de la réglementation IVDD actuelle et future IVDR régissant les produits de diagnostic in vitro. » a expliqué M. Ronan Boulmé, Directeur GRC chez ABL.

ABL propose une suite complète de produits de gestion des soins de santé, notamment Nadis®, TherapyEdge®, ViroScore®, SeqHepB, DeepChek®, UltraGene®, VisibleChek®, HepatiC®, BacterioChek, MicrobioChek et le DPM utilisé pour la gestion, le suivi et la personnalisation des données et des patients. Depuis 2012, certains produits ABL sont marqués CE-IVD. En 2020, ABL a obtenu le marquage CE-IVD pour ses tests DeepChek®-HIV ainsi que pour son test UltraGene® Combo2ScreenSARS-CoV-2 et pour son test UltraGene® SARS-CoV-2 Multi Variants Deletions V1 et son test UltraGene® Triplex. Les autres produits sont actuellement disponibles à des fins de recherche uniquement. Veuillez consulter l'équipe ABL pour plus d'informations sur le statut d'enregistrement des produits de l'ABL sur votre territoire.

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