



Company Name	CAC Croit Corporation <a href="https://www.croit.com">https://www.croit.com</a>
Name of Representative	President & CEO Hisashi Takahashi

**CAC Croit forms a business alliance with Formedix and Innovion to Enhance CDISC Services and Support for Global Submissions**

Tokyo, December 6, 2017 - CAC Croit Corporation headquartered in Tokyo, Japan (President & CEO: Hisashi Takahashi, "CAC Croit") is pleased to announce that CAC Croit has entered into a business alliance with Formedix Limited headquartered in Glasgow, the United Kingdom (Chief Executive Officer: Mark Wheeldon, "Formedix") and Innovion BVBA headquartered in Putte, Belgium (Chief Executive Officer: Peter Van Reusel, "Innovion") to provide CDISC services and support for global drug submissions to regulatory authorities.

**1. Background and Purpose of the Business Alliance**

The Japanese Pharmaceuticals and Medical Devices Agency (PMDA) has started accepting electronic study data for drug applications in Clinical Data Interchange Standards Consortium (CDISC) formats since October 2016. Shortly the submission of clinical data in CDISC formats will become a regulatory requirement and pharmaceutical companies will be required to file new drug applications using these global standards.

On this basis, CAC Croit formed a business alliance with Formedix and Innovion, leading providers of the CDISC services, with the aim of providing faster, automated, cost effective CDISC conversion services to a very high quality. Through the business alliance with CAC Croit, Formedix and Innovion will also expand their businesses and increase sales in Japan.

Formedix and Innovion have a wealth of experience in drug submissions in Europe and the US, particularly with the Food and Drug Administration (FDA). For this reason, CAC Croit can deliver our enhanced CDISC submission support services by leveraging the knowledge and experience of Formedix and Innovion, and CAC Croit's knowledge of submissions in Japan. We believe that by using our submission support, pharmaceutical companies in Japan will further improve efficiency in submission-related operations.

**2. Future development**

CAC Croit, in alliance with Formedix and Innovion, will start providing automated CDISC conversion and global submission services. In cooperation with Innovion, we further plan to develop services for anonymization of clinical trial datasets. We will undertake initiatives to utilize anonymization services in the data management domain which will include medical information database management.



## ***Press Release***

Date of issue: December 6, 2017

---

CAC EUROPE LIMITED (CAC Europe) will be the point of contact when CAC Croit provides services abroad through this alliance.

### **3. Corporate profile**

- **Formedix**

Founded in 2000 by CEO Mark Wheeldon, Formedix is a leading supplier of clinical trial automation software and services. With offices in the US and the UK, its CDISC standards software solutions and services are utilized globally by Pharmaceutical, CRO, and Biotechnology organizations.

<http://www.formedix.com/>

- **Innovion**

Innovion, a Belgian-based clinical trial consulting firm, was founded in 2016 by Managing Director Peter Van Reusel, a certified CDISC CDASH and SDTM trainer and the Chair of the European CDISC Coordinating Committee (E3C).

<http://www.innovion.be/>

- **CAC Croit Corporation**

CAC Croit is a CRO that provides services for a wide range of areas including clinical development, submissions and postmarketing surveillance on a contract basis. By utilizing its advantage in IT, it offers an end-to-end service, from system consulting for pharmaceutical development to system development, operation, and maintenance. Our CDISC related services include the conversion of clinical data for over 120 studies to the CDISC SDTM and data for over 50 studies to ADAM. We also have experience of attending consultations with authorities.

<https://www.croit.com/en/>

Contact:

Corporate Planning Division, CAC Croit Corporation

Tel.: +81-3-5623-4676