

	<b>Formular</b>
	<b>GBG EDC System User Agreement</b> <b>CONFIDENTIAL</b>

**Please send this form to: GBG Forschungs GmbH Fax +49 6102-7480-440**  
**This form is required only once for each EDC-system unless user role changes or the user switches to a different center.**

		GBG Area	
GBG PMA approval (n.a. for Electronic UA) Initials:	Signature:	Date: __ / __ / ____	
		EDC System	
Trial(s)	Role(*)	MedCODES	Marvin
		<input type="checkbox"/>	<input type="checkbox"/>
<b>Role (*)</b>			
1 = Principal Investigator, 2 = Deputy-Investigator, 3 = Sub-Investigator, 4 = Study Nurse, 5 = Pharmacist, 6 = CRA			
Other Role (to be defined by GBG only): _____			
GBG Area GBG EDC-System Activation (date and initials): __ / __ / ____ _____			

## GBG EDC System User Agreement

between

the **GBG Forschungs GmbH**, Dornhofstraße 10, 63263 Neu-Isenburg, **Germany**,  
 Subsequently known as „GBG“

and the **Applicant** (details below)

**Salutation:**             Ms         Mr

**Last Name:**            \_\_\_\_\_

**First Name:**            \_\_\_\_\_

**E-Mail:**                    \_\_\_\_\_

**GBG Site Number:**    \_\_\_\_\_ (if available)

**Company Name:**        \_\_\_\_\_

**Address:**                    \_\_\_\_\_

    \_\_\_\_\_

**Zip Code, City:**        \_\_\_\_\_

**Country:**                    \_\_\_\_\_

**§ 1**

The Applicant receives the permission for data access to the GBG EDC System for the period of active participation in a GBG Trial.

For this purpose, a personal user name and a personal password will be provided by the GBG to enable the Applicant to access the GBG MedCODES EDC system. The initial password must be changed on first login. The password must be renewed every 6 months.

In order to provide the new user with access to the MARVIN EDC system, a study-specific internet link (URL) and a personal username are sent to the user by email from the GBG. Instructions for accessing the MARVIN system are contained in the email. The password for the MARVIN system must be renewed every 180 days.

The password has to be kept secure and confidential and is meant for the use of the applicant only. The user name or password is not allowed to be given to any third party.

**§ 2**

The following changes are to be reported immediately to the GBG:

- a. The Applicant's role in the GBG EDC system changes
- b. The Applicant's email address or name changes
- c. The Applicant's center changes
- d. The Applicant leaves a center

**§ 3**

User-specific activity data is stored when using GBG EDC system to comply with the legal requirements (e.g. GCP; local law), to check for abuse and for failure analysis.

This information includes time, IP address, client information, queries and changes to the database.

Data are stored in accordance with the legal requirements of the German Drug Law (AMG) for a minimum of 10 years.

**§ 4**

The Applicant agrees that an e-Signature in the GBG EDC system is the legally binding equivalent of the hand-written signature, according to ICH-GCP Guidelines, Section 4.9.1-3 and to the FDA 21 CFR Part 11. The Applicant confirms the submission of complete and accurate information.

**§ 5**

The Applicant is obliged to keep all GBG clinical trial data confidential. The Applicant is not entitled to share or process the data available with any third party.

**§ 6**

The Applicant is obliged to read the GBG EDC User Manual available in the system after login.

---

Date	Signature of Applicant	Name in Block Letters
------	------------------------	-----------------------