

1) Scope of Services

The Institute for Medical Informatics, Statistics and Documentation at the Medical University of Graz, Auenbruggerplatz 2, A-8036 Graz (the "Provider") provides registered users (the "User") with access to this self-serve Randomization Service for Multi-Center Clinical Trials (the "Service"), that runs exclusively on the Internet, subject to the terms and conditions set forth in this document (the "Terms and Conditions").

The Provider will offer reasonable levels of continuing technical support to assist Authorized Users in the use of the Service. Technical support is provided via email during normal trading hours (local time i.e. CET/CEST).

Additional Services, particularly for statistical consultation, have to be stipulated separately.

2) Conclusion of Contract with the Provider

The contract enters into force as soon as the Provider receives the filled out Trial Registration Form of the User. Immediately after receipt of these data subject to section 13 the Service for this Clinical Trial will be enabled by the Provider.

3) Period of Validity and Termination

The contract is basically valid until the duly ending of a Clinical Trial and its billing and payment.

The termination of the Randomization for a Clinical Trial can be initiated by the Trial Coordinator via email at any time. After that the User will be invoiced but only to the number of randomizations by the time of end or termination. If the number of randomizations included in the basic fee will not be exceeded, there is no right of partial refund, except the money-back-guarantee (according to section 6 below).

Except in default of payment the Provider is not entitled to terminate a Randomization for a Clinical Trial. The Provider reserves the right to suspend or terminate the account in case of misuse of the Service according to section 4 below.

4) Obligations of the User

The User himself/herself is responsible to gain access to the Service and has to take into consideration that this access may involve third party fees (such as Internet service provider or airtime charges). Additionally, the User must ensure to provide all equipment necessary to access the Service.

In consideration of the use of the Service, the User agrees to provide true, accurate, current and complete information about himself/herself as prompted by the registration form (such information being the "Registration Data") and maintain and promptly update the Registration Data to keep it true, accurate, current and complete.

If the User provides any information that is untrue, inaccurate, noncurrent or incomplete, or the Provider has reasonable grounds to suspect that such information is untrue, inaccurate, noncurrent or incomplete, the Provider has the right to suspend or terminate the account and refuse any and all current or future use of the Service (or any portion thereof).

The User is responsible for saving his/her Clinical Trial's data with the help of the export function which has been made available to the User.

It is particularly important to note that with double-blind studies, the generated blinding codes must be retained by the user and be stored, available for emergencies, according to their own security guidelines.

It is the User's duty to keep confidential his/her account and password and to restrict access to his/her computer. Moreover, the User agrees to accept responsibility for all activities that occur under his/her account or password.

5) Remuneration and Terms of Payment

Remuneration is announced at www.randomizer.at. Any increase of remuneration during the entire trial is excluded.

An invoice covering the administration fee and the included quantity of randomizations will be forwarded to the billing address at the time of the trial's activation, and is due within 30 days of issue. Further invoices will be forwarded monthly, quarterly or semi-annually, depending on the Trial Coordinator's choice.

Additional services will be charged separately.

6) Money-back-Policy

A money-back-guarantee with full refund becomes effective if – within a period of 6 month after trial activation – no more than 10 patients have been randomized into a trial and the Trial Coordinator confirms trial termination.

7) Delay of Payment

Disregard of the terms of payment entitles the Provider to deny the User's further access to the Service. The Provider will inform the Trial Coordinator thereof before.

8) Limitations of Warranties, Liability

The provision of this service is provided on an "as is" and "as available" basis. Any material downloaded or otherwise obtained through the use of the service is done at the User's own discretion and risk and that the User will be solely responsible for any damage to his/her computer system or loss of data that results from the download of any such material.

The provider expressly disclaims all warranties of any kind, whether expressed or implied, including, but not limited to, the implied warranties of merchantability, fitness for a particular purpose, and non-infringement.

Additionally, the Provider cannot guarantee either the reliability, punctuality, or security, nor the accuracy or reliability of the results of the Service or that the Service is defect free.

If technical errors are brought to the Provider's attention, the Provider will try to correct them. Thus the User has to state precisely by e-mail why the Service is in error, documenting as clearly as possible why or how the error occurred. The User's help and cooperation is needed to handle requests quickly and efficiently.

The Provider shall not be liable to the User or any third party for any special, incidental, indirect or consequential damage of any kind, or any damage whatsoever, including, without limitation, those resulting from loss of use, data or profits, whether or not the Provider has pointed out to the possibility of such damage, and on any theory of liability, arising out of or in connection with the use of the Service.

The liability of the Provider is limited by the amount outlined in section 5.

The Provider makes no guarantee that through the use of the Service the rights of a third party are not infringed upon or that no other damages are caused. The Provider is not liable for infringement of rights upon third parties or any other damages caused to third parties.

The User agrees to indemnify, hold harmless, and waive all claims against the Provider and its employees, including reasonable attorneys' fees, made by any third party due to or arising out of content he/she makes available through his/her use of the Service, his/her connection to the Service, his/her violation of the Terms and Conditions, or his/her violation of any rights of another.

9) Privacy

The Provider will not use the Registration Data for any other purpose than the Service. The Provider will neither use this information for marketing nor pass the data on to any third party.

10) Data protection

The security of the trial information and the User's personal one is very important to the Provider, and he agrees to use reasonable endeavours to protect the received information. The Provider has installed security measures to protect the system against loss, misuse or alteration of information that he has collected from the User.

However, no data transmission over the Internet or any wireless network is completely safe. As a result, the Provider cannot ensure or warrant the security of any information, written, oral or online, provided by the User, and the User provides it at his/her own risk. Nonetheless, the Provider tries the utmost to protect all kind of information.

11) Modification and Severability

The Provider reserves the right to change the site, policies, and these Terms and Conditions at any time at its sole discretion without notice to the User.

The most current version of the Terms and Conditions is made available on the website: www.randomizer.at.

If any provision or provisions of these Terms and Conditions shall be held to be invalid, illegal, unenforceable or in conflict with the law of any jurisdiction, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.

12) Applicable law, place of jurisdiction, final provisions

All legal relations between the Provider and the User shall be subject exclusively to the law of the Republic of Austria. Graz shall be the exclusive place of jurisdiction for all disputes arising from this agreement.

No modification or claimed waiver of any provision of this agreement shall be valid except by written amendment signed by the Trial Coordinator and the authorized representatives of the Provider.

If the User becomes aware of any violations of these Terms and Conditions, the User is requested to notify the Provider as soon as possible. Although the Provider cannot guarantee that action will be taken as a result of the notification, any feedback is welcome.

13) Austrian Consumer Protection Act of 1979

The Services may not be acquired by consumers as defined in the Austrian Consumer Protection Act of 1979 in its current form. The Provider explicitly retains the right to inform any consumer wishing to fill out or having filled out the registration form that no contract is or has been concluded. However this is only an information, as no offer is given by the Provider.