Med Uni Graz *Pioneering Minds*

European Society for Immunodeficiencies

Department of Pediatrics and Adolescent Medicine
Division of Pediatric Hemato-Oncology
Auenbruggerplatz 38, A-8036 Graz

Assoc.-Prof. Dr. Markus G. Seidel
Professor of Translational Pediatric Hematology and Immunology
Chair ESID Registry Working Party 2022-2026

markus.seidel@medunigraz.at
Tel +43 / 316 / 385-80215

To all Participants of the ESID Registry
and all those interested

Graz, July 1st, 2024

Newsletter ESID Registry July 2024

Dear Colleagues and Friends of the ESID Registry,

It has been a while since I last communicated with you, but the silence does not reflect the high level of activities of the steering committee and myself "behind the curtains" that are going on in the registry working party. To avoid spam and keep communications brief, let me outline the content and see the details:

1) **Overhaul of the technical platform of the ESID registry and change of operator**

2) **Call for two study/survey participations with very tight deadlines (July 21st!), both offer offer study group collaborative coauthorship if succesful:**

   a) **Lung involvement in IEI/PID**
   https://stuz-redcap.ukl.uni-freiburg.de/surveys/?s=F9W8PWYPAKMK3XWJ

   b) **IEI/PID Registry landscape in the world – your experience**
   https://bildungsportal.sachsen.de/umfragen/limesurvey/index.php/847313?lang=en

3) **List of recently completed studies and publications**

4) **Initiative of a 30 years anniversary paper of the ESID registry, current epidemiology, statistics, outcomes, and challenges**

5) **Prolongation of the ESD registry – ERN-RITA (RITA registry) collaboration**

6) **Miscellaneous**

There will be follow up communication later this summer with templates for documents you may need regarding the technical platform change. With this I would like to whish everyone a great summer. ***May you all be happy and free from suffering! May you all be at peace!***

Sincerely yours
Markus Seidel

See next pages for details!

In detail:

1) *Migration of the ESID registry technical platform to Castor-Edc® as new operator:*
In order to maintain system and data security, the technical platform of the electronic (online) ESID registry, both the input mask and the database, originally established in 2014, will be converted to a new operating system managed by a professional operator, Castor-Edc (based in the Netherlands), by the second half of 2024. The decision was failed unanimously by the ESID board in February 2024 after careful evaluation and testing of more than 6 different options/proposals in the last 1.5 years. This system is designed to incorporate advanced security protocols and measures and ensure the protection of data in compliance with industry standards and all applicable laws. The new registry will be constantly maintained and technically updated; the operator provides guarantees and has assumed contractual obligations to comply with all regulatory requirements and certifications such as GDPR, ISO27001, FDA 21 CFR part 11, ICH-GCP, and HIPAA. Key updates for patients and their information include enhanced security measures and a change in the storage location and operator from the Medical University of Freiburg, Germany, to Castor-Edc, Netherlands. All the data will remain encrypted in the registry and unchanged in terms of quality, quantity, and access authorizations. For new patients, the informed consent forms will be adapted and templates will be distributed after approval from the ethics commission. For the centers, an amendment of the study protocol and of the center agreement will also be distributed after approval of the local ethics commission, due in summer 2024. Centers who disagree with the upgrade and amendment may choose to opt out and terminate their participation, but cannot stay in the old system because the existing platform will be closed. Importantly, because this is a necessary security upgrade, already registered patients do not need to reconsent. As a key feature, the new system will provide the possibility to create new add-on (sub)-study CRFs decentrally, facilitating YOUR new research study using ESID registry data. Furthermore, there will be the long-awaited automated center reports (center dashboard), delivering your center's performance with regards to local epidemiology and stats in comparison to the entire ESID registry cohort to your doorstep/inbox at a regular interval. For those interested to be informed ahead, here are some training recommendations (especially the one on "data entry"): https://academy.castoredc.com/courses/category/edc-cdms

2) *Calls for study/survey participation (both deadlines July 21st 2024):*

a) **Pulmonary diseases** significantly impact patients with Inborn Errors of immunity (IEI), yet detailed knowledge and current treatment regimens remain limited. Therefore, we deeply appreciate your valuable contributions and invite you to participate in the study "Spectrum of Pulmonary Manifestations in Patients with inborn Errors of immunity (IEI) – an ESID Registry Study". The deadline for this survey, aiming to result in a collaborative publication, is July 21. We are planning to include the contribution of your completed survey in the pubmed-searchable group-collaborator list at the end of the article. Your participation involves answering 10 mandatory questions along with optional extended questions. You can stop and resume the survey entry for each patient at any time by following the instructions provided in the link above. Once you have finalized your entries, please make sure to press "Submit" as the data will not be transferred otherwise. Please feel free to contact johanna.krista@tum.de with any questions regarding the survey. School of Medicine and Health, TUM; together with Ellen D Renner, Gerhard Kindle, Klaus Warnatz.
Study: **https://stuz-redcap.ukl.uni-freiburg.de/surveys/?s=F9W8PWYPAKMK3XWJ**

b) **Registry Landscapes for Inborn Errors of Immunity (IEI).** On behalf of the ESID registry working party steering committee, we would like to understand how many active registries for inborn errors of immunity (IEI) for patient data entry exist. This shall become part of a manuscript and give an overview of the global registry landscape and of possibilities for further collaborations with the ESID registry (ESID-R). We would be grateful, if you could take 3-5 minutes to answer our survey about your national, international and regional registry involvement (if existent). We are planning to include the contribution of your completed survey in the pubmed-searchable group-collaborator list

at the end of the article. We thank you for your time and contribution! Catharina Schuetz, Michael Albert, Svetlana Sharapova. Survey: https://bildungsportal.sachsen.de/umfragen/limesurvey/index.php/847313?lang=en

3) *Recently completed and/or published studies involving ESID registry data:*
   a. Recently closed, yet unpublished studies currently under data analysis and manuscript preparation (to my knowledge, errors excepted): *IDDA score; malignancies in IEI*; *JAGN1*.
   b. For publications, please always check with the website/publications. Please note that study authorships should comply with the publication rules as published on our website. In principle, if patients from your center are included in a research study, you or at least one representative of your center should be named as collaborative author, PubMed searchable (study group authorship), at the end of the article, while only those who actively contributed in the respective project are listed as full authors on the first page of a manuscript:

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4) *Initiative of a 30 years anniversary paper of the ESID registry, current epidemiology, statistics, outcomes, and challenges*
The extended ESID registry steering committee has been working on a current and historical/retrospective data analysis to provide the most comprehensive and fascinating report on patients and studies in the field of IEI/PID from Europe, preliminary results of which to be presented at the ESID 2024 meeting and submitted to a high-end Journal this fall. Ideas or suggestions are welcome (to me or SC members).

5) *Prolongation of the ESD registry – MERITA / ERN-RITA (now: RITA registry) collaboration*
The pilot project of the MERITA registry, launched by my predecessors and under previous ESID presidents, was considered very successful and entered a new phase. Common data elements of the ESID registry, a minimal epidemiological set of parameters shared with other European registries in the fields of rare immunological diseases (i.e., Eurofever, Pharmachild), will be forwarded to the RITA registry to combine efforts and avoid redundancies. The data transfer is handled under existing agreements and patients' consents on academic research cooperations, but the wording will be amended in the new Center Agreement template asap.

6) *Miscellaneous*
   a. *New ESID website:* planned 2023, delayed, but being worked on
   b. *ESID registry "office":* admin staff = IT staff Dr. Gerhard Kindle, whose work for the registry has been highly appreciated and resulted in numerous publications, is working together with IT expert Stephan Rusch on the migration of the registry to the new operator. Ther will be limited administrative support until end of August and we were promised increased assistance from the ESID association management, specific negotiations, personell decisions and details pending.
   c. *Authorships:* there have been questions about authorship rules in registry publications. Please see the "publication guidelines" on our website and feel free to contact me with your comments. The registry steering committee has always strived to be fair and honour intellectual input and work as well as data acquisition proportionally in their contribtutions to new manuscripts.
   d. Legal matters: The registry steering committee, myself as chair, as well as the board has been advised by an ESID-employed (jurist-) data protection officer and a lawyer, and proceedings regarding the registry and center affairs have been double checked with the Medical University of Graz data protection officer, legal department, and ethics commission.
   e. Registry Session at www.ESIDmeeting.org 2024 on Friday, 7.30h ;(Oct. 18, Marseille), PLEASE JOIN, you are very welcome!

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Prof. Markus Seidel, M.D.
Chair, ESID Registry Working Party
Graz, July 1st, 2024