

BUILDING A NATIONAL ePAG GROUP

ePAG ITALY

April 2020

Activity	Creation of the Italian ePAG group in collaboration with the Italian National Alliance.
Area	<i>Governance, Dissemination and Integration of the ERNs at national level</i>
Duration	6 months for the creation of the ePAG Italy group with the collaboration of the National Alliance
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1. SUMMARY

i The need to develop strategies dedicated to the Integration of the European Reference Networks (ERNs) into the National Health Systems has encouraged the creation of the Italian group of ePAG Advocates. Thanks to the efforts of some ePAG Advocates, the collaboration of EURORDIS and of the Italian Rare Diseases Alliance (UNIAMO), the Italian group of ePAGs Advocates “ePAG Italia” was founded in 2019. During the 2019 EURORDIS Membership Meeting in Bucharest, an Executive Committee was elected in order to ensure the effective implementation of the objectives and to provide strategic and operational supervision.

All Italian ePAG Advocates have been invited to join and to collaborate with the Executive Committee and regular web conferences are organized. The group includes more than 45 Italian ePAG Advocates from 17 different ERNs¹. The ongoing activities to consolidate the Italian ePAG group range from the organization of training courses to the dissemination of the ERNs at national level.

The main objective is to establish a national framework aimed at proactively contributing and facilitating the integration of the ERNs into the Italian National Healthcare System. In addition, the group aims at establishing a transversal group of Italian ePAG Advocates to share good practices, create a contact point for the Italian patient organizations and for national institutions. The contact point is aimed to explain patients’ involvement in ERNs, overcoming the current language barriers and consolidating the national rare disease network, encouraging their involvement also in the different initiatives on ERNs and rare diseases in Italy. This group is providing a framework for the integration of the European activities in the national scenario and therefore contributing to the actual integration of ERNs into the national health systems.

¹ The 45 members of ePAG Italy are involved in 17 ERNs: ENDO ERN, ERN EPICARE, ERN EURACAN, ERN EUROBLOODNET, ERN EUROGEN, ERN EURO-NMD, ERN GENTURIUS, ERN GUARD-HEART, ERN ITHACA, ERN LUNG, ERN ReCONNET, ERN RITA, ERN-RND, ERN SKIN, ERN TRANSPLANT-CHILD, METABERN, VASCERN.

2. INITIAL SITUATION

i The participation of patient representatives into the ERNs was established thanks to the creation of 24 European Patient Advocacy Groups (ePAGs). Currently, more than 290 patient representatives are engaged in the ERNs to ensure that the patients' voice is heard in the activities of the ERNs. In this context, the need to join efforts in order to promote the integration of ERNs into the National Health Systems still remains one of the most important topics to be effectively addressed in a comprehensive and transversal strategy. So far, two main documents were published regarding the Integration of ERNs into the National Health Systems, one is the "[*EURORDIS Recommendations on the Integration of European Reference Networks \(ERNs\) into National Health Systems*](#)", published in November 2018 and the second is the "[*Statement of the ERN Board of Member States on Integration of the European Reference Networks to the healthcare systems of Member States*](#)", adopted on 25th June 2019. These documents have highlighted how crucial and indispensable it is to act promptly towards this integration in order not only to ensure that all patients affected by rare and complex diseases can access the ERNs systems, but also to facilitate the sharing of knowledge at national, regional and local level. In this context, a small group of Italian ePAGs and representatives² of the Italian Rare Diseases Alliance (UNIAMO), decided to join forces and to establish a national group of ePAG Advocates with the main aim of creating an active group of patient representatives that could contribute to this relevant action.

3. CONTRIBUTION TO PATIENT ENGAGEMENT AND/OR IMPROVEMENT OF CARE

i The creation of ePAG Italy was promoted by 3 Italian ePAG Advocates that started the process by contacting both EURORDIS and the Italian Rare Disease Alliance. After some internal brainstorming, EURORDIS was asked to support in the initial discussion aimed at drafting the possible scopes and the mission of the group. The initial discussion included the President of UNIAMO and one additional Italian ePAG Advocates that contributed to the first steps of the creation of the group.

Once an agreement was reached, the group identified each Italian ePAG Advocate that was involved in an ERN and an email was sent to inform about the creation of the group. A first web-conference was organized to agree on the first steps, that included the creation of a survey to outline the mission and the scopes of the group, and in the meantime, to summarize the profiles of the members of the group. The survey was immediately circulated among the members of the group and for each member a profile was created to understand the role and level of engagement in the ERN, location of the ePAG for future involvement in meetings, professional background and expertise in patient engagement. The survey was very helpful also to get to know each other better and to plan the future activities of the group.

Once the group was established, a press release was published with the support of UNIAMO and forwarded to the Italian rare disease communities, including Institutions, National competent authorities, Italian ERN Coordinators and Members, ERN Board of Member States Italian Representative, etc.

During the 2019 EURORDIS Membership meeting in Bucharest, a face-to face meeting was organized with the Italian ePAG Advocates attending the conference, while the other ePAG Advocates could join the meeting virtually via Zoom. During the meeting, an Executive Committee was elected to coordinate

² From ERN EpiCare, ERN ReCONNET, ERN RITA, ERN ITHACA.

the group and ensure that the expected results of the activities are achieved. The Executive Committee is composed of 6 elected members of ePAG Italy plus a delegate of UNIAMO, that will ensure the exchange of information and engagement in the national initiatives on rare diseases. The Executive Committee takes care of the coordination of the group, with a specific active role in the communication and administration of the group. The appointment of the members of the Executive Committee has a duration of 3 years. After 3 years, a new election will be organized and the former members can be elected again. A spokesperson is identified among the members of the Executive Committee.

Currently, the members of the Executive Committee are:

- Claudio Ales - ERN GENTURIUS
- Isabella Brambilla - ERN EPICARE
- Loris Brunetta - ERN EUROBLODNET
- Ilaria Galetti - ERN RECONNET
- Diana Marinello - ERN RITA
- Annalisa Scopinaro – Representative of UNIAMO
- Diana Vitali - ERN - ENDOERN

The group meets in monthly web-conferences and a virtual archive was created to store documents and important records, such as minutes of the meetings and presentations. ePAG Italy has also established an email address³ and a Facebook page that are managed by the Executive Committee. In addition, the group has two WhatsApp group, one for all the members of ePAG Italy and one for the Executive Committee.

On 29th February 2020, during the International Rare Disease Day, the group launched the ePAG Italy website: <https://www.epag-italia.it/>. The website provides information in Italian on the 24 ERN and on the Italian ePAGs involved in the different ERNs. A search engine enables the user to search in which ERN a specific disease is followed. The website will, in the near future, inform on the ERN initiatives and will also have a section dedicated to Patients' Education in which the webinars realized by ePAG Italy will be published. The publication of a regular Newsletter is also planned for 2020.

The creation of ePAG Italy intends to contribute actively to different scenarios:

1) **Inform.** Create a point of contact for the Italian communities of rare and complex diseases patients, where they can find reliable and updated information on ERNs and on other initiatives related to rare diseases. This is already in place thanks also to the ePAG Italy website.

2) **Collaborate.** Establish more close collaboration with all the Italian rare diseases organizations, especially the ones not yet involved in the ERN system, in order to enable the identification of needs and priorities to be taken at European level. This is considered one of the priorities of the group for the activities of the next years and so far the Members of the Executive Committee have participated as speakers in different meetings and educational events, informing the audience on ERNs and ePAG Italy and proposing collaborations with other Italian rare diseases organizations.

3) **Cooperate.** Create a transversal group of ePAGs where experiences can be shared and efforts can be joint to reach crucial goals not only at European level, but also at national, regional and local level. This is one of the main added value recognized by the whole group and the monthly web-conferences are the perfect place for these discussion.

4) **Educate.** Organize educational activities aimed at enabling Italian ePAG Advocates to engage in the different Working Groups, Task Forces and other initiatives related to rare and complex diseases also at national, regional and local level. The main educational activity planned so far as the realization of webinars on transversal topics, such as Registries and ERN assessment of the new HCP Applicants. More webinars are already planned for 2020.

5) **Advocate.** Build a national network of patient organizations to advocate for the improvement of the

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lives of rare and complex diseases patients with a group of experienced and knowledgeable patient advocates. Together with point 3, this can be considered one of the actions to be addressed by the group.

4. SUCCESS FACTORS

i The main success factor was definitely the **willingness of collaboration among the Italian ePAGs** involved in the different ERNs, that decided to establish ePAG Italy. The fact that many Italian ePAGs knew each other and were already collaborating has also helped the process.

Another important success factor is the **collaboration and the active engagement of UNIAMO**, that is supporting ePAG Italy in the different initiatives, such as the involvement of some members of ePAG Italy as speakers in regional/national events.

The **launch of the website www.epag-italia.it** has also contributed to the success of the group, as it provides important information to the Italian communities of rare and complex diseases patients, especially but not only on the ERNs. Many Italian ePAG Advocates contributed to the creation of the content of the website in Italian and to the creation of the long list of diseases covered by each ERN (still ongoing).

Currently, the group is also organizing a **series of webinars in Italian on relevant topics** (such as Registries, the process of approval of medicines, the European Medicine Agency, overview of the ERNs and of the role of the ePAGs, the process of assessment of HCPs in the ERNs, etc.), which will highly contribute to the success of the group. The webinars organized so far were considered very useful from the participants as they presented the topics from the point of view of Patient Representatives/ePAG Advocates and provided practical examples on the topics that could be easily applied in practice by the other ePAG Advocates.

Another success factor is definitely **the participation of ePAG Italy to the Italian Conference on ERNs** organized in Pisa by ERN ReCONNET. The event included the participation of the 3 Italian ERN Coordinators, the President of UNIAMO, two Representatives of ePAG Italy and HCPs Representatives from the vast majority of ERNs and other patient organizations. The event was the first national event that included representatives of so many ERNs and the fact that ePAG Italy was invited to give a presentation at the beginning of the conference can be acknowledged as a success. The conference was a great occasion to discuss experiences, challenges and unmet needs of both the patients' and the medicals' needs and it highlighted that a lot of efforts still need to be done at national level and that ePAG Italy needs to take part to the discussions in order to ensure that also the ERN patients' voice is heard.

5. LESSONS LEARNED

i **Building a national ePAG group can provide a crucial added value in achieving tangible results for the patient community of rare and complex diseases** and in the integration of the ERNs into the National Health System. The group is, in fact, focused in being included in specific working groups for rare diseases, alongside the National Alliance; in this way the requests of the ERNs' transversal working groups can be addressed with one common voice and integrated in the national/regional Healthcare Policies and initiatives. We are looking forward to the collaboration with the Italian Rare Diseases Alliance (which can really help in this process, for example by promoting the integration of ePAG Italy in Working Groups and Task Forces) and with the Italian representative in the ERN Board

of Member States, Dr. Domenica Taruscio, as well as the National representatives of the ERNs.

Other challenges are:

- Since not all the ePAG Advocates are affiliated to the National Rare Disease Alliance, it is crucial to **work together and maintain the independence of the group**. Within ePAG Italy, this was overcome by guarantying one permanent sit within the Executive Committee to a representative of the National Rare Disease Alliance. This ensures that the group is always updated and integrated in the main national/regional initiatives and that the group acts with a stronger single voice.

– **Inclusion of newly appointed Italian ePAG Advocates in ePAG Italy**. It is important to be updated by EURORDIS on the appointment of the new Italian ePAGs in the different ERNs. EURORDIS could for example, ask to the newly appointed ePAG to agree to forward their contact to the ePAG Italy Executive Committee and inform them about the existence of the Italian ePAG group.

- **Need for more Knowledge, Empowerment, News on the ERNs and exchange of experiences**. The results of the survey and the exchange of experiences among the ePAGs Advocates, gave a clear picture of the different level of engagement in the ERNs and the different backgrounds of the Advocates.

Many ePAGs still need to be more informed on the functioning of the ERNs and on the potentiality of their active engagement with the ERN Coordination Team and with the ERN clinicians.

In this framework, ePAG Italy showed a great potential in overcoming many challenges, especially in the empowerment of the ePAG Advocates and in exchanging not only good practices but also in providing prompt information on the most important issues on the ERNs that are needed to participate in their activities. This was for example very important in the assessment of the new ERN Applicants. Many ePAGs have expressed the need to be more informed on the process and on how they could contribute to the HCPs assessment. A webinar was organised by two Italian ePAG Advocates within a few days to explain in details the legal framework of the assessment and to exchange experiences and knowledge on how the ePAGs were already involved. The discussion was particularly helpful for many ePAG Advocates, as after the webinar they had the appropriate knowledge on the topic and they could immediately engage with their ERN to get involved in the assessment process.

Another webinar was organised on a very “hot” topic: the participation of the ePAGs in ERN Registries. Considering that 19 ERNs were funded to create ERN Registries, there was a high need from many Italian ePAGs to know more about Rare Disease Registries and how to be involved in the ERN for this topic. One of the Italian ePAG Advocate presented a webinar on Registries, with specific information on the ERN Registries, on the involvement of the ePAGs in some ERN Registries and providing the experience of the creation and management of a European Rare Disease Registry. This webinar was also considered very useful by the participants as they could learn the basic knowledge on the Registry and it provided practical examples that can be used by the other ePAG Advocates to be more engaged within the Registry of their ERN.

For all these reasons, more educational activities are needed to empower our Italian ePAG Advocates.