



PROFILE Registry FAQs

Q. What is the PROFILE Registry?

A. The PROFILE (Patient Registry and Outcomes For breast Implants and anaplastic large cell Lymphoma etiology and Epidemiology) Registry is a collaboration between ASPS, The PSF and the FDA to better understand the role of breast implants in the etiology of anaplastic large cell lymphoma (ALCL) in order to determine whether an association exists between the device and the disease.

Q. Where can I find more information on PROFILE?

A. Additional information about PROFILE can be found on the following website: thepsf.org/profile

Q. Who can submit a case of BIA-ALCL to PROFILE?

A. PROFILE is currently only open to physicians practicing in the United States, with plans to accept international cases in the near future.

Q. How do I report a case to PROFILE?

A. Visit thepsf.org/profile and click "Report a Case" or contact ALCL@plasticsurgery.org and the PROFILE data coordinator will send you instructions on how to sign up to participate.

Q. How do I sign up to participate?

A. Visit the Sign-up Portal to sign up for PROFILE using the following link: <https://psrn.plasticsurgery.org/Signup/Login.aspx>

Q. Do I have to sign any agreements in order to submit details about my case to the PROFILE Registry?

A. Each practice must sign a Business Associate Agreement (BAA) and Data Warehousing Agreement with our registry vendor, FIGmd, as well as a PROFILE Data Submission Acknowledgement and Consent in order to participate in PROFILE. These agreements can be signed online within the Sign-up Portal: <https://psrn.plasticsurgery.org/Signup/Login.aspx>.

Q. What kind of information will be collected in the PROFILE Registry?

A. The PROFILE Registry captures the data necessary to describe patient demographic characteristics and other medical history, implant procedure information, characteristics of the implant, clinical presentation, pathologic findings, clinical course, treatment and treatment outcomes of patients with primary BIA-ALCL.



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Q. How do I enter data?

- A.** Visit The Plastic Surgery Registry Network (PSRN) to log in to your account using the following link: <https://psrn.plasticsurgery.org/Dashboard/Login.aspx>. Click "Add Case" to enter data directly into the PROFILE Case Report Form (CRF).
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Q. Will I have access to the data I entered into PROFILE?

- A.** Yes. You can download a PDF version of all of your completed Case Report Forms (CRFs).
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Q. Can I have someone else in my practice enter data for me?

- A.** Yes. You may add "Designated Users" to enter data on your behalf when you register to participate in PROFILE.
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Q. I forgot my username and password to log in to my account. How should I proceed?

- A.** Visit the PSRN using the following link: <https://psrn.plasticsurgery.org/Dashboard/Login.aspx/>. In the white login box, click "I forgot my password". You will be prompted to enter the email address that is associated with your account. Once you provide this, an email will be sent to you with a link to reset your password. If you do not receive an email within 15 minutes, please check your junk folder and/or contact psf.support@bot.figmd.com.
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Q. Will it cost me money to participate?

- A.** PROFILE case submission is free of charge. However, if your site requires an IRB review, you will be responsible for this expense.
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Q. What will I get if I participate?

- A.** You will not be compensated for your participation in the PROFILE Registry. The data you contribute will provide insight into the safety of breast implants and also help address any concerns raised by the FDA or other agencies.