



Peer-to-Peer Advice Service

www.p2padvice.org

Instructions for Use

February 2021

Agenda



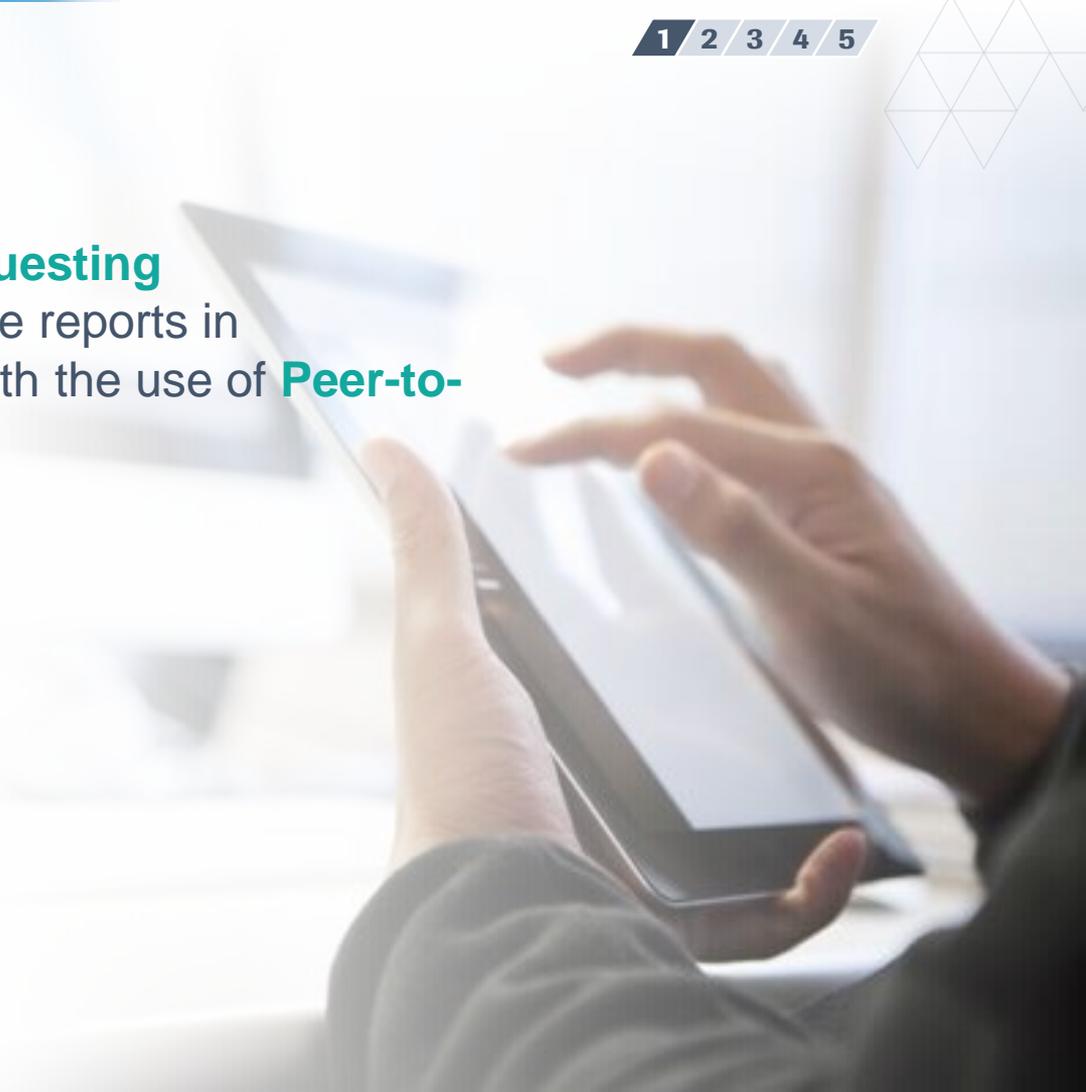
- 1** Overview
- 2** Peer-to-Peer Advice Service Overview
- 3** Patient Case Submission
- 4** FAQ
- 5** Glossary



Instructions Overview

The objective of this document is to familiarize you as **Physician requesting an advice** on a Foundation Medicine reports in comprehensive genomic profiling with the use of **Peer-to-Peer Advice service**, in particular:

- 1. How to submit a patient case**
- 2. Explain the roles**
- 3. Inform on legal and compliance liabilities**





Peer-to-Peer Advice Service Overview

What is the P2P Advice Service?

Physicians requesting advice upload their questions regarding a specific (anonymized) Foundation Medicine report onto the Peer-to-Peer Advice platform.



Experienced **Experts** can select open questions and answer them.

What is the Peer-to-Peer Advice?

An online platform to support communication and knowledge sharing between medical professionals to improve treatment decision process.

Designed around the needs of treating physicians which would like to discuss FMI patient cases with their peers.

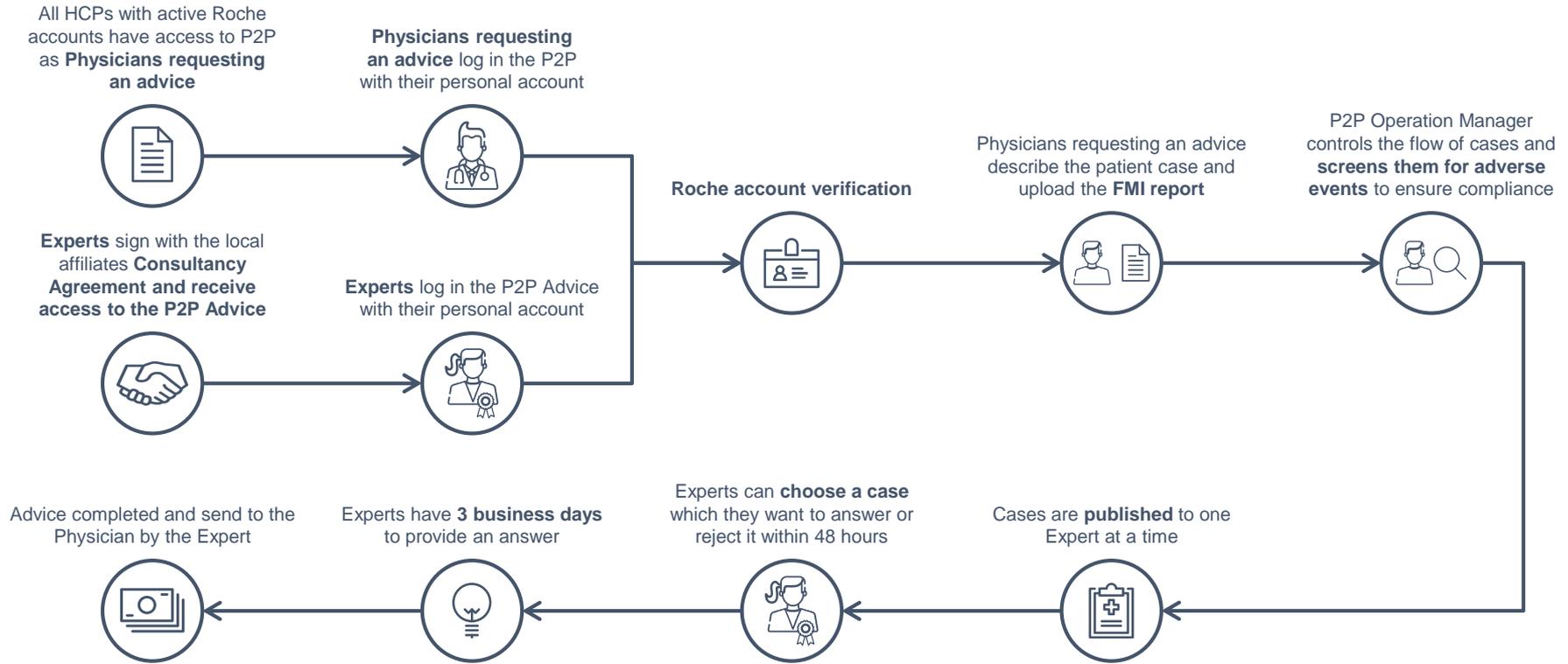
It is **complementary to molecular tumor boards** format.

Peer-to-Peer Advice is supported by Roche but **has no direct Roche involvement**



Peer-to-Peer Advice Service Overview

How does the service work?



Patient Case Submission – A guide for Physicians requesting an advice



Submit a patient case and get an advice

Key steps

1. How to submit a case and seek advice?
Process overview
2. Accessing p2padvice.org
3. Accepting Terms and Conditions
4. Profile overview
5. Create New case
 - a. Upload FMI Report
 - b. Describe your case and formulate a question
 - c. Choose Experts and provide selection order
6. Receiving an advice
 - a. New case waiting to be selected by an Expert
 - b. Case selected
 - c. New response from Expert
 - d. Responsibility for the treatment decision
 - e. Ask another question or complete the case
7. Follow-up question
8. Follow-up answer
9. Case completed
10. P2P Support contact



How to submit a case and seek an advice?

Process overview





Accessing Peer-to-Peer Advice

What is the Peer-to-Peer Advice Service?

Please sign in.



Gain access to information, news and resources about our medicines and the therapy areas in which they are used. ✓

[Forgot your password?](#)

[Don't have an account?](#)



Remember my username

Please sign in.

Go to www.p2padvice.org and login with your Roche account (RODiP).

If you don't have an account, click "**Don't have an account?**" the process of creating an account can take 1-5 business days



Accepting Terms and Conditions

After logging in you will be asked to agree to the following terms and conditions which ensure the compliance of the whole process:

- I will not disclose in the Tool any data that identifies a specific patient unless I have obtained a written data privacy consent from the patient
- I while obtaining specific advice from qualified experts through the Service, I remain fully responsible for any treatment decision
- I hereby indemnify and hold Roche fully harmless from any damages, losses and claims in relation to and arising from the use of the Service

In addition to this you must also acknowledge that:

- You are responsible for the correctness and completeness of any content uploaded
- The Service is provided only in English
- Roche does not have access to or any influence on the content of the advice provided by the qualified experts
- Full responsibility for the treatment decision lies with the treating physician
- You are solely responsible for the patient's data privacy and shall ensure that no identified or identifiable data is uploaded unless the written consent of the patient has been obtained for the specific purposes of the Service. A patient consent template can be found under the following link (link to the downloadable document with the patient consent)
- The uploaded data will be deleted after 1 calendar year or at the moment of discontinuation of the Service, whichever term is shorter
- The tool is not intended to adverse events reporting. If you wish to report adverse events, please report directly to [local drug safety departments](#)



Profile overview

P2P Advice



Here you can change your user settings

Open cases 1

Here you can find all your cases which are submitted and waiting to be selected and answered

Draft cases 7

Here you can find cases which you started but didn't submit

Completed cases 6

Here you can find all your cases which have been already answered and are closed

FAQ Here you can find answers to the most frequently asked questions

Logout Here you log out safely from P2P Advice. Where is a significant difference between closing the browser and clicking logout.

Share P2P Advice Here you can invite other doctors to join the platform

For support or questions check the:

[Peer-to-Peer Advice Users Handbook](#)

Here you can download user handbook

or contact us:
support@p2padvice.org



Create new case

P2P Advice



Open cases **1**

Welcome to P2P Advice!

*You have consulted **13** out of total **49** patient cases submitted by other physicians.*

CREATE NEW CASE +

You can start by clicking
“**Create New Case**”
button.



Create new case

Upload of FMI report

New case

Patient information

The information you provide here is the basis for patient case assessment. Please enter all the relevant information regarding your patient in English.

NOTE! Please remember you are responsible for patient personal data, surname, date of birth, please make sure you obtain patient consent

FMI Report

FMI Report Summary

Edit missing or different details



| | | | |
|------------------------------|---|--|---|
| <i>Gender</i> MALE | <i>Patient's Age</i> 58 | <i>Cancer Type</i> Prostate cancer (NOS) | |
| <i>Test Type</i> | FoundationOne@Liquid CDx | <i>Genomic Findings</i> | ATM splice site 72+2delT MLL2 W5065fs*7 TP53 E294* |
| <i>Biomarker Findings</i> | Blood Tumor Mutational Burden 3 Muts/Mb Microsatellite status Cannot Be Determined Tumor Fraction- 13% | | |

US F1LCDx 5.pdf



Here you have to upload an FMI report and formulate your question. The basic information from the report will be extracted automatically. The full report will be available as a downloadable attachment.



Create new case

Describe your case and formulate a question

- + Pathology report
- + Patient's condition and comorbidities
- + Treatment history

Other important information

- + CT/MRI/Radiology
- + Laboratory reports
- + Family history

My question

The question is mandatory to be able to submit your case.

SAVE AS DRAFT NEXT >

In the next step you can describe your patient case in more details - these fields are optional but they will be very helpful for Experts to better understand the case.

Finally there is a mandatory field for your question. We advise to formulate it as precise as possible to avoid any doubts on the Expert side.

You don't have to submit your case immediately. You can save as a draft and come back to it later. Once you're sure the description of your case is complete you can click **"NEXT"** to move to the next step.



Create new case

Select Expert

Please set prioritisation of 3 Advice Givers to whom you would like to send your question.

Please note that an Advice Giver may not select your case to answer. In that case you can always select a different Advice Giver.

Search

| Priority | Title | Name | Biography | Primary Specialization | Secondary Specialization | Primary Institution | Country |
|----------|-------|---|-----------|---------------------------|---------------------------|---------------------|-----------|
| - | | Dr. Alan Tan | | Genitourinary oncology | Hemato oncology | | USA |
| 1 | | Dr. Valery Breder | | Molecular oncology | | | Russia |
| 2 | | Dr. Armin Gerger | | Molecular oncology | Gastrointestinal oncology | | Austria |
| 3 | | Dr. Munveer Bhangoo | | Gastrointestinal oncology | Gynecologic oncology | | USA |
| | | Dr. Ben George | | Hemato oncology | Gastrointestinal oncology | | USA |
| | | Dr. Stephen Fox | | Pathologist | Molecular pathology | | Australia |
| | | Dr. Shai Izraeli <small>(Only pediatric cases)</small> | | Pediatric oncology | Hemato oncology | | Israel |
| | | Dr. Ido Wolf | | Gastrointestinal oncology | Breast oncology | | Israel |
| | | Dr. Joseph Chao | | Gastrointestinal oncology | | | USA |

Before submitting your case, you will be asked to select Experts from whom you'd like to receive an advice. You can choose up to three experts registered in P2P Advice and prioritize them from 1 to 3. An Expert with priority 1 will receive your case as the first one. If he will not be able to provide an answer on time, the case will be redirected to an Expert with priority 2 and eventually to an Expert with priority 3.



Create new case

Select Expert

| Priority | Title | Name | Biography | Primary Specialization | Secondary Specialization | Primary Institution | Country |
|----------|-------|---------------|-----------|------------------------|---------------------------|---------------------|---------|
| ▼ | Dr. | Alan Tan | | Genitourinary oncology | Hemato oncology | | USA |
| ▼ | Dr. | Valery Breder | | Molecular oncology | | | Russia |
| ▼ | Dr. | Armin Gerger | | Molecular oncology | Gastrointestinal oncology | | Austria |

To make a decision which Expert to select, you can click on the “?” icon to unfold a biography of an Expert. This way you can learn more about his/her research and professional experience.



Dr. Alan Tan
Genitourinary oncology

✕

Biography: Dr. Alan Tan is an assistant professor in the Division of Hematology, Oncology and Cell Therapy at Rush Medical College. As the Director of GU Medical Oncology, Dr. Tan is dedicated to improving the lives of patients with genitourinary tumors. He specializes in kidney cancer, bladder cancer, prostate cancer and melanoma. He also has an extensive background in hematologic malignancies. Dr. Tan has clinical research interest in designing and implementing clinical trials to test novel immunotherapies and targeted therapies for melanoma, renal cell carcinoma, prostate cancer and urothelial malignancies. He also has interest and expertise in precision genomic cancer medicine, identifying molecular alterations that will serve as targets for individualized treatment strategies. Dr. Tan serves as executive officer for the GU section of Alliance for Clinical Trials.

Professional experience:

- Assistant Professor, Rush University - Chicago, Illinois
- Director of Genitourinary Malignancies
- Executive Officer – Alliance for Clinical Trials

Education:

- St. Georges University School of Medicine

Additional information:

- Member of the American Society of Oncology, Society for Immunotherapy of Cancer, and American Society of Hematology
- Former Director of clinical research and hematology at Cancer Treatment Centers of America

Publications

- A Phase 1, open-label, multi-center, dose escalation and dose expansion study of NKTR-225 as a single agent in relapsed or refractory hematological malignancies and in combination with daratumumab as a salvage regimen for multiple myeloma – American Society of Hematology 2019, Society for Immunotherapy of Cancer 2020
- DREAMM-6: Safety and tolerability of belantamab mafodotin in combination with bortezomib/dexamethasone in relapsed/refractory multiple myeloma (RRMM) - oral presentation at ASCO 2020
- Advances in the systemic management of follicular lymphoma
Oncology Times: July 20, 2018 - Volume 40 - Issue 14 - p 1,5,6,19-19



Create new case

Select Expert

oncology

| | | | | |
|-----------------|-----------------|--------------------|--------------------|--------|
| Associate Prof. | Umut Dişel | Molecular oncology | Hemato oncology | Turkey |
| Dr. | Robert Galamaga | Hemato oncology | Molecular oncology | USA |

Items per page: 50 1 - 16 of 16 |< < > >|

Your case will be sent to the selected advanced genomic profiling experts for review.

SEND CASE > SAVE AS DRAFT BACK

Now you can submit the case with the “Send case” button.



Receiving an advice

New case waiting to be selected by an Expert

P2P Advice



Open cases

Draft cases

Completed cases

FAQ

Logout

For support or questions contact
support@p2padvice.org

Welcome back to P2PA!

CREATE NEW CASE +

Open cases

LAST UPDATED ON JUL 26, 2019, 11:30 AM

NOT SELECTED BY ANY ADVICE GIVER YET

| Gender | Patient's Age | Cancer Type | Test Type |
|--------------------|---|----------------------------|--|
| | | Colon adenocarcinoma (CRC) | |
| Cancer Stage | | | |
| Question | This is the test question for the Handbook? | | |
| Biomarker Findings | Microsatellite Status MS-Stable Tumor Mutation Burden TMB-Low (3 Muts/Mb) | Genomic findings | BRAF N581S FLT3 amplification APC S1415fs*7 CDK8 amplification TP53 W146* |
| Treatment History | | | |

CASE DETAILS →

Now you can see your case in "Open Cases". The case is waiting to be selected by Expert.



Receiving an advice

Case selected

P2P Advice



Open cases

Draft cases

Completed cases

FAQ

Logout

For support or questions contact support@p2padvice.org

CREATE NEW CASE +

Open cases

LAST UPDATED ON JUL 16, 2019, 9:19 PM

YOUR CASE IS BEING REVIEWED

| Gender | Patient's Age | Cancer Type | Test Type |
|--------------------|---|------------------------|---|
| DATE OF C... | | Breast carcinoma (NOS) | FoundationOne CDx™ |
| Cancer Stage | | | |
| Question | Sample training question? | | |
| Biomarker Findings | Microsatellite Status --MS-Stable Tumor Mutation Burden --TMB-Intermediate (8 Muts/Mb) | Genomic findings | ERBB2 amplification MYC amplification ARID1A Q199* RAD21 amplification TBX3 P403fs*230 |
| Treatment History | | | |

CASE DETAILS →

When your case will be selected you will receive an email notification and you will notice also a new label informing that **YOUR CASE IS BEING REVIEWED.** Since now the Expert who selected your case has 3 business days to send you an answer.



Receiving an advice

New response from Expert

P2P Advice



Open cases

Draft cases

Completed cases

FAQ

Logout

For support or questions contact support@p2padvice.org

You have 1 new response.

CREATE NEW CASE +

Open cases

LAST UPDATED ON JUL 17, 2019, 11:37 AM

NEW RESPONSE

| Gender | Patient's Age | Cancer Type | Test Type |
|--|---------------------------|------------------------|--------------------|
| DATE OF C... | | Breast carcinoma (NOS) | FoundationOne CDx™ |
| Question | Sample training question? | | |
| VK Doctor Vasil Krastev | Primary institution | | |

OPEN RESPONSE →

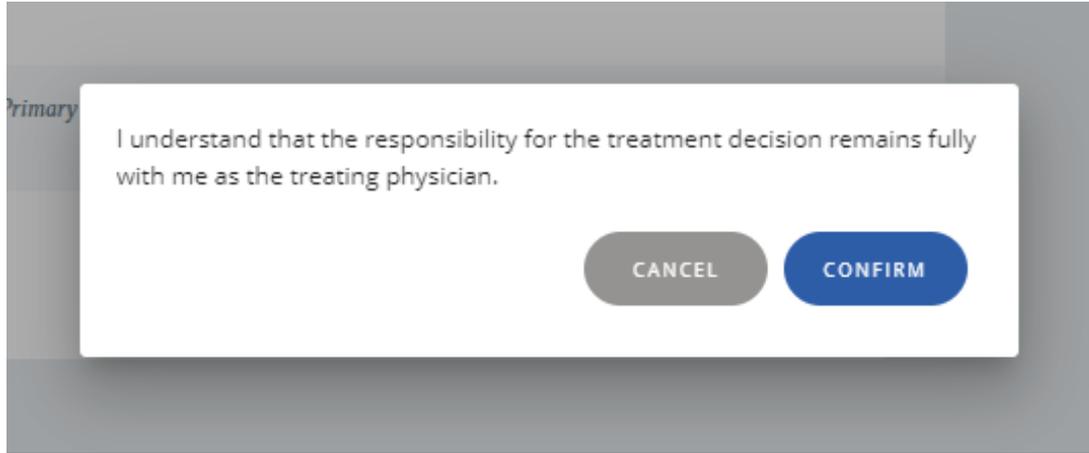
If the Expert sends you an answer, you will be notified with an email.

You can see the answer in P2P in the Open cases page.



Receiving an advice

Responsibility for the treatment decision



Before opening the answer you will be reminded that the responsibility for treatment decisions is fully yours.



Receiving an advice

Ask another question or complete the case

Response from Dr. Vasil Krastev

This is sample training answer

Information from FMI Report

| Gender | Patient's Age | Cancer Type | Test Type |
|--------------------|---|------------------------|--|
| DATE OF C... | | Breast carcinoma (NOS) | FoundationOne CDx™ |
| Test Type | FoundationOne CDx™ | Genomic findings | ERBB2 amplification MYC amplification ARID1A Q199* RAD21 amplification TBX3 P403fs*230 |
| Biomarker Findings | Microsatellite Status --MS-Stable Tumor Mutation Burden --TMB-Intermediate (8 Muts/Mb) | | |

FoundationOne CDx Report Breast CDx ERBB2.pdf

ASK ANOTHER QUESTION MOVE TO COMPLETED CASES

After reading the answer from the Expert you can decide either to **ASK ANOTHER QUESTION** or **MOVE TO COMPLETED CASES**.



Follow-up question

Asking Expert for additional clarifications

Your question

Another sample training question?

SEND >

If you found the answer from the Expert insufficient or need clarification, you can **ask another question**.



Follow-up answer

Responding Physician

 *Response from*
Vasil Krastev *Primary institution*

Contact  vasil.g.krastev@accenture.com

Your Question

Sample training question?

Response from Dr. Vasil Krastev

This is sample training answer

Follow-Up Question

Another sample training question?

Follow-Up Response

Another sample training answer

In the Case details you can see all your questions and answers from Expert



Case completed

End of the process

P2PAdvice



- Open cases
- Draft cases
- Returned cases
- Completed cases**
- FAQ
- Logout

1

For support or questions contact support@p2padvice.org

Completed cases

LAST UPDATED ON JUL 17, 2019, 11:52 AM

COMPLETED

| | | | |
|--------------------------------------|---|---|---|
| <i>Gender</i> DATE OF C... | <i>Patient's Age</i> | <i>Cancer Type</i> Breast carcinoma (NOS) | <i>Test Type</i> FoundationOne CDx™ |
| <i>Cancer Stage</i> | | | |
| <i>Question</i> | Sample training question? | | |
| <i>Biomarker Findings</i> | Microsatellite Status --MS-Stable Tumor Mutation Burden --TMB-Intermediate (8 Muts/Mb) | <i>Genomic findings</i> | ERBB2 amplification MYC amplification ARID1A Q199* RAD21 amplification TBX3 P403fs*230 |
| <i>Treatment History</i> | | | |

[CASE DETAILS →](#)

Your case will be completed if you decide to move your case to **Completed** after the first answer from the Expert.

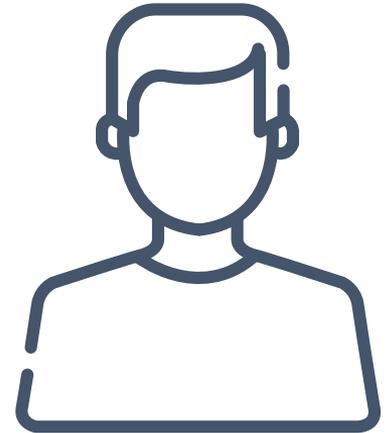
It will be automatically completed after the Expert answers your second (follow-up) question.

After that you can still see your case with all questions and answers in the Completed cases page.



P2P Support

In case of any problems or questions related with the Peer-to-Peer Advice please reach out to:
support@p2padvice.org
We will respond within 1 business day.





Frequently Asked Questions

For Physicians requesting an advice

How many patient cases can I submit?

You can submit as many patient cases with FMI testing (CDx and Liquid) as you want. Note: FMI reports for patients under clinical trials are not eligible.

What data and documents do I need to submit a case?

There are two mandatory sections which you need to fill in every case. These are: FMI report (CDx or Liquid) and your question to the experts. There are also other sections which you can use to describe the case in more detail, but they are optional. However, the more details you include, the easier it will be for the experts to provide you with a satisfactory answer.

What FMI reports are supported by P2P Advice?

As of now, P2P Advice supports all types of FMI reports (CDx, Liquid, Liquid CDx and Heme) from 2019 onwards.

Can I share patient identifiable data in the patient case that I am submitting in P2P Advice?

Yes, but only when you obtain patient's consent to process, transfer and disclose personal data. You can find the document template [here](#). If you do not have patient's consent you need to make sure that there are no patient identifiable data in the case description or any documents which you upload with the case.

What are patient identifiable data?

Identifiable data are any data which enable identification of a person, e.g. name, surname, address, email, telephone/fax number, dates (except year), ID numbers (e.g. social security, medical record, health plan, account, certificate / license), biometric identifiers, full-face photographic images and any comparable images, or any unique identifying number or characteristic.

Why do I have problems with submitting the FMI report? I receive a failure message when I try to upload it to the case.

Most likely you're trying to upload a scan of the FMI report or any other file format to which the original FMI report has been transformed (e.g. an image file *.JPEG; *.PNG). FMI reports can be uploaded only in the open PDF format. P2P Advice can read the basic information like genomic or biomarkers findings from the original reports.



Frequently Asked Questions

For Physicians requesting an advice

When will I receive an answer?

It depends when your case will be selected by an expert. However, after your case is selected, the expert has 3 business days (Monday-Friday) to submit an answer.

Can I ask additional question to an expert after I receive an answer?

Yes, after you receive your first answer, you can ask a follow-up question. You have 2 business days (Monday-Friday) to do so. However, please remember that you can ask only one additional question and the expert has 2 business days to provide you an answer. After that your case will be automatically closed.

In case you are not be satisfied with the received insights, you can always submit a new patient case to investigate the case further.

What can I do if my case is not selected by any expert?

In this situation you can always move the case back to draft, reformulate your question and select other experts in P2P Advice.

What happens if my case has been selected but I haven't received any answer?

After the case selection experts have 3 business days (Monday-Friday) to provide an answer. If they fail to do so, your case will be returned to other experts selected for your respective case.

When is the case completed?

The case is completed when you click on the "Complete case" button. You can do that after receiving the first answer from the expert. The case will be completed automatically when you receive the answer to your follow-up question.

Who should I contact if I have any problems with the service?

In case of any questions or problems with P2P Advice you can contact support@p2padvice.org. We will provide you support within 1 business day (Monday-Friday during CET business hours).



Glossary

Expert – A healthcare professional acting as an expert on treatment based on genomic profiling who provides advice on specific patient cases submitted to P2P Advice application

Physician requesting an advice – A healthcare professional seeking a consultation on a patient case with an existing Foundation Medicine report (F1CDx and F1L)

P2P Operations Team – A team operating the service on behalf of Roche but is not a Roche employee, supporting users in case of problems or questions regarding the Peer-to-Peer Advice. P2P Operations Team scans also for and reports Adverse Events (AE)

FoundationOne CDx Report (FMI Report CDx) - the FDA-approved broad companion diagnostic (CDx) that is clinically and analytically validated for solid tumors. The test is designed to provide physicians with clinically actionable information — both to consider appropriate therapies for patients and understand results with evidence of resistance — based on the individual genomic profile of each patient’s cancer. Every test result includes microsatellite instability (MSI) and tumor mutational burden (TMB) to help inform immunotherapy decisions. (source: <https://www.foundationmedicine.com/genomic-testing/foundation-one-cdx>)

FoundationOne Liquid CDx Report (FMI Report Liquid) – the next-generation liquid biopsy test for solid tumors utilizing circulating tumor DNA (ctDNA). This test may be considered to complement solid tissue results or when tissue is not ideal (source: <https://www.foundationmedicine.com/genomic-testing/foundation-one-liquid>)

