

### Document information

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### **Revision history**

Revision	Revision name	Revision date	Summary of changes
r1 SG-03570-r1-EN 2023-07-18 Initial release of the document.		Initial release of the document.	
r2	SG-03570-r2-EN	2023-11-28	Updated various sections to reflect user interface updates. Updated cohort search and filtering sections. Updated cohort creation section. Added cohort duplicating and bookmarking sections.
r3	SG-03570-r3-EN	2024-02-09	Updated various sections to reflect user interface updates. Updated definition of terms.

#### Symbols table

Symbol	Title
$\bigcap$ i	Consult instructions for use or go to www.sophiagenetics.com
REF	Catalog number
$\triangle$	Caution
•••	Manufacturer
EC REP	Authorized Representative in the European Community
	Importer

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#### Conventions

This document uses the following conventions:

► For more information	A cross-reference to a related or more detailed topic.
[]	Text enclosed in square brackets indicates optional qualifiers, arguments or data.
<>	Text enclosed in angle brackets indicates mandatory arguments or data.

#### Intended use

SOPHiA CarePath is a cloud-based software intended to be used for retrieving and displaying clinical data across modalities for a tailored cohort. SOPHiA CarePath is intended to be used by clinical researchers to support their research assessment.

Based on the user request, SOPHiA CarePath displays a set of clinical research data and descriptive statistics for a tailored cohort in comparison to another cohort from the user's account or from the network.

SOPHiA CarePath is not intended to create, analyze or modify any clinical data, nor does it generate any direct diagnosis or potential findings, it is intended to be used as a research use-only tool.

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### Definition of terms

#### Account

Generalized term for user ID, credential, identity, subject or entity within a directory service, representing an individual, group, system, device, function, service, etc.

#### **Application**

Represents a pre-defined cohorting dataset where application criteria such as cancer type or data source is already applied at the population level.



Represents the total number of patients from the population matching the cohort criteria.



Eastern Cooperative Oncology Group. Physical performance scale used to assess patient physical condition.

#### Excluded

Represents the total number of patients removed from the population and the cohort because they contain one or multiple unknown values in applied criteria or clinical outcomes.



#### **GDPR**

General Data Protection Regulation



#### **HIPAA**

Health Insurance Portability and Accountability Act



### **IDMC** criteria

Criteria filtering patient on their Independent Data Management Committee intermediate study inclusion status.

#### **IFU**

Clinical Application-specific Instruction for Use. Contains information to allow the safe and proper use of an application. Also includes directions for use, maintenance, troubleshooting, and warnings and limitations.



#### LDH

Lactate dehydrogenase



#### OS probability

Overall Survival probability. Probability that the patient has not died at a given time period after the start of a treatment.



The p-value measures how likely it is that any observed difference between groups is due to chance. Being a probability, P can take any value between 0 and 1.

#### PD-L1

Programmed death-ligand 1

#### PFS probability

Progression-Free Survival probability. Probability that the patient remains free from disease progression or death at a given time period after the start of a treatment.

#### **Population**

Represents the total number of patients matching the population criteria.



#### Remaining

Represents the total number of patients from the population that don't match to the cohort criteria.

#### **RUO**

Research Use Only - not for use in diagnostic procedures.

## 1 Definition of terms (continued)

S

### Scope (clinical)

Category of criteria to filter patient based on clinical study enrollment.

#### Study (clinical)

Criteria to filter patient that are part of a given clinical study.



#### Widgets

Dashboard components providing an overview and/or shortcuts to dedicated platform modules, for example, the My Genomic Analysis Requests widget provides an overview of the latest analysis runs and quick access to selected, or all, analysis runs.

### 2 Data processing

Data hosted in SOPHiA CarePath is processed under the conditions defined in the SOPHiA GENETICS General Terms and Conditions.



For information on data processing operations, please contact the SOPHiA GENETICS Data Protection Office (privacy@sophiagenetics.com).

## 3 Storage and handling

There are no storage and handling requirements for SOPHiA CarePath.

## 4 Components and setup

No additional setup is required for SOPHiA CarePath.

### 5 About SOPHiA CarePath

SOPHiA CarePath is a cloud-based software intended to be used by clinical researchers. SOPHiA CarePath combines health data from multiple modalities, enabling users to define a population of patients of interest within user accounts or from the SOPHiA GENETICS network. This population can be further refined into a tailored cohort. When a cohort is created, SOPHiA CarePath enables cohort outcome and statistical description visualization and comparison with the other patients from the defined population. SOPHiA CarePath is for Research Use Only and does not create, analyze, or modify clinical data, or generate direct diagnoses.

### 5.1 Users

The main target users of SOPHiA CarePath are oncologists and clinical researchers.

### 6 Installation

There are no installation requirements for SOPHiA CarePath.

For information on how to access SOPHiA CarePath, refer to "Access SOPHiA CarePath" on page 16.

### 6.1 Web browser requirements

SOPHiA CarePath is accessed using the following browsers:

- Google Chrome, version 100 or later
- · Microsoft Edge, version 99 or later

### 6.2 Hardware requirements

SOPHiA CarePath was developed to support  $1280 \times 800 \text{ px}$  as a minimum display size. For optimal performance, we recommend using a standard HD screen  $1920 \times 1080 \text{ px}$ .

### 6.3 Recommended Internet connection speed

Recommended	Preferred	Ideal
> 20Mbps	> 100Mbps	> 200Mbps

| Table 1 Recommended Internet connection speed

### 7 Secured access

SOPHiA CarePath provides secured access, to ensure the security of your SOPHiA GENETICS applications and data.

### 7.1 Access SOPHiA CarePath

To access SOPHiA CarePath for the first time, you need to sign up.

To sign up to SOPHiA CarePath:

- Go to the SOPHiA CarePath website.
   https://platform-fra.sophiagenetics.com/carepath/carepath-ui/home
- 2. Select Sign up now.
- 3. Enter your email address.



You must use the same email address that was used to create your account.

Contact SOPHiA GENETICS support for help.

For more information, refer to "Support information" on page 39.

4. Select Send verification code.

A verification code is sent to the email address you entered in Step 2.

- 5. Enter the verification code.
- 6. Enter your name and create a new password.

Your password is checked immediately. You will be prompted if your password does not comply to security requirements.

7. Select *Create* to complete the sign up process.

## Secured access (continued)

### 7.2 Sign in

To sign in to SOPHiA CarePath:

- Go to the SOPHiA CarePath website. https://platform-fra.sophiagenetics.com/carepath/carepath-ui/home
- 2. Enter your email address and password.
- 3. Select Sign in.



To use SOPHiA CarePath, you must accept the SOPHiA CarePath terms and conditions. If you don't want to be prompted to accept the terms and conditions every time you sign in, select the *Do not show this message again* check box.

When a new version of SOPHiA CarePath is deployed, the SOPHiA CarePath terms and conditions are displayed, and must be acknowledged, even if you previously selected the Do not show this message again check box.



You may be prompted for multi-factor authentication, for example, entering a code sent to you by email.

### 7.3 Sign out

To sign out from SOPHiA CarePath:

- From any SOPHiA CarePath view, select your avatar to access your user menu.
- Select Sign out.

### 8 SOPHiA CarePath views

SOPHiA CarePath consists of the following views:

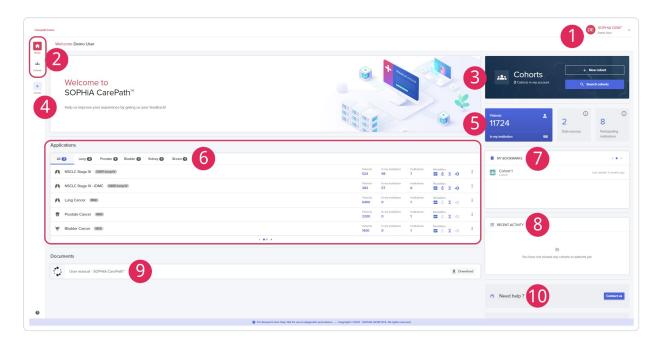
- CarePath homepage
- · Cohort list view
- · Cohort detail view

The views are accessed from the navigation bar.

The *Cohort* detail view is accessed from the *Cohorts* list view.

### 8.1 CarePath homepage

The CarePath homepage is the main view that you see when you log in. It displays user information and provides navigation to other views of CarePath.



Number	User avatar - displays your personal information, and allows you to sign out by selecting the <i>Sign out</i> button.		
1			
2	Navigation bar - allows you to switch between the CarePath homepage and the <i>Cohort</i> list view.		
3	<b>Cohorts</b> widget - displays the number of cohorts on your account, and allows you to access the <b>Cohort</b> list view or create new cohorts.		
4	Create button- allows you to create a new cohort.		
5	Cohorting metrics - displays the number of patients and datasets integrated in CarePath as well as the number of institutions providing data to these integrated datasets.		
6	Applications widget - displays a list of existing and announced cohorting applications with general information and metrics, and allows you to create a cohort in the scope of the selected application.		
7	My Bookmarks widget - displays bookmarks that you create, and allows you to directly access bookmarked cohorts.		
8	Recent Activity widget - displays the list of recently opened cohorts and allows you to directly access a selected cohort.		
9	Documents widget - allows you to download the user manual.		
10	<b>Support</b> widget - allows you to contact SOPHiA GENETICS support by email or phone, and access the SOPHiA GENETICS website.		

Figure 1: CarePath homepage

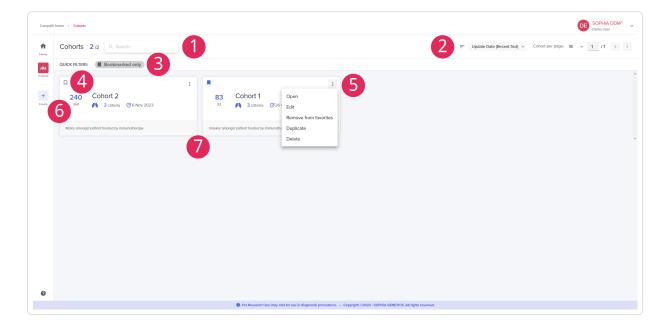
### 8.2 Cohort list view

The *Cohort* list view displays all cohorts that you are permitted to view. You can search cohorts and filter the list of cohorts to only display bookmarked cohorts.

Each cohort card displays basic information about the cohort. You can use the ellipsis menu on the cohort card to open, edit, bookmark, duplicate, and delete the cohort.

The *Cohort* list view also allows you to create new cohorts.

For more information on creating a cohort, refer to "Create a cohort" on page 27.



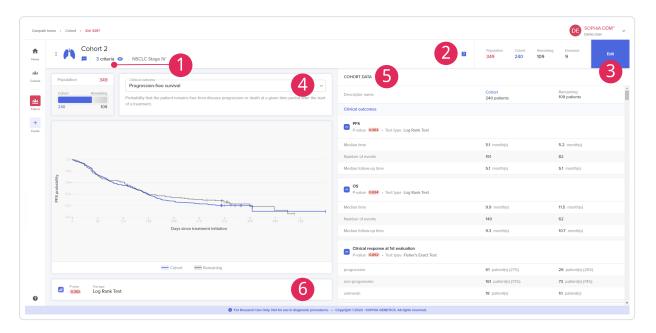
Number	Description		
1	Search box - allows you to search for specific cohorts.		
2	Sorting option - sorts cohorts by name and update date.		
3	Bookmark filter - toggles the <i>Bookmarked only</i> filter on and off.		
4	Bookmark option - bookmarks the cohort.		
5	Ellipsis menu - gives you access available actions for the cohort.		
6	Create button - allows you to create a new cohort.		
7	Cohort cards - displays all cohorts that you are permitted to view.		

| Figure 2: Cohort list view

### 8.3 Cohort detail view

The *Cohort* detail view displays the outcome and statistical description of the selected cohort compared to other patients from the original population used to create the cohort. It also allows you to edit the cohort name, description, and cohort or population criteria.

You can access the *Cohort* detail view by selecting a cohort from the *Cohort* list view.



### Number Description

criteria o - opens the Criteria list panel.

To close the *Criteria list* panel, click anywhere outside the panel. For more information, refer to "Criteria list panel" on page 22.

- 2 Patient numbers section displays the following data:
  - Population represents the total number of patients matching the population criteria.
  - · Cohort represents the total number of patients from the population matching the cohort criteria.
  - · Remaining represents the total number of patients from the population that don't match to the cohort criteria.
  - Excluded represents the total number of patients removed from the population and the cohort because they contain one or multiple unknown values in applied criteria or clinical outcomes.
- 3 Edit button allows you to edit the details and criteria of the cohort.

  For more information on editing a cohort, refer to "Edit a cohort" on page 33.
- 4 Clinical outcome drop-down allows you to switch the view of the Clinical outcome graph.

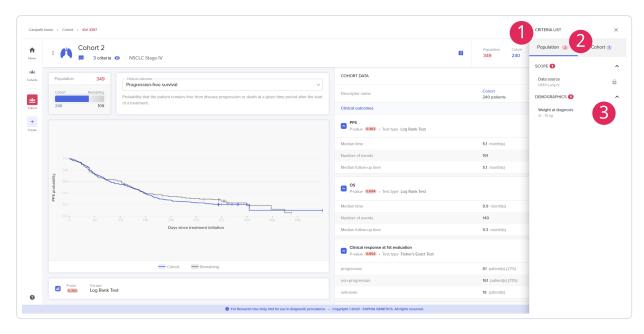
  For more information on the Clinical outcome graph, refer to "Switch views of the Clinical outcome graph" on page 32.



The vertical ticks on the *Progression-free survival* and *Overall survival* graphs correspond to censor events (the number of days where the patient follow-up ended without any PFS or OS events) for one or more patients of the associated group.

- Cohort data statistical description table contains the cohort data divided by descriptors.
  For more information on the cohort data, refer to "Statistical description table" on page 23.
- 6 Shows the calculated p-value associated with the displayed outcome graph. For more information on p-values, refer to "P-value calculation" on page 24.

| Figure 3: Cohort detail view



Number	Description		
1	Criteria list panel.		
2	Criteria tabs - allow you to switch between population criteria and cohort criteria.		
3	List of criteria - allows you access and edit specific criterion details		

| Figure 4: Criteria list panel

### 8.3.1 Statistical description table

The table below lists possible statistical description values for different types of variables.

Variable type	Example	Definition	
Continuous variables	Median	The median value of the descriptor of the associated group.	
	25th percentile	The 25th percentile value of the descriptor of the associated group.	
	75th percentile	The 75th percentile value of the descriptor of the associated group.	
	Unknown	The number of patient from the associated group for which the category is unknown.	
Categorical variables with two possible choices	Yes or No Progression or Non- progression	For each category, the number of patients from the associated group that belongs to this category is displayed as well as the percentage of patient of the group it represents.	
	Unknown	The number of patients from the associated group for which the category is unknown.  They are excluded from the group percentage computation.	
Categorical variables with more than two possible choices	Smoking status	For each category, the number of patient from the associated group that belongs to this category is displayed as well as the percentage of patient of the group it represents.	
	Unknown	The number of patient from the associated group for which the category is unknown. They are excluded from the group percentage computation.	
Survival variables	Median time	The number of months since beginning of the treatment for which the PFS or OS probability reaches 50% in the associated group.	
	Number of events	The number of PFS (progression or death) or OS (death) events observed in the associated group.	
	Median follow-up time	The median value of the number of months since the beginning of the treatment for which patients have been followed in the associated group.	

| Table 2 Types of variables used in the statistical description table

### 8.3.2 P-value calculation

The p-value measures how likely it is that any observed difference between groups is due to chance. Being a probability, P can take any value between zero and one.



When the p-value calculation conditions described in  $\underline{\underline{\text{Table 3}}}$  are not met, the p-value number and statistical test name are replaced with --.

The table below lists methods of p-value calculation for different types of variables.

Variable type	Example	P-value calculation
Continuous variables	Age	Based on the Mann-Whitney U test. It is possible to calculate the p-value only if the number of patients in each group for which this variable have a known value is equal to or greater than five.
Categorical variables with two possible choices	Yes or No Progression or Non- progression	Based on Fisher's exact test. It is possible to calculate the p-value only if the sum of the observed frequencies for each choice both in the population and in the cohort is equal to or greater than one.
Categorical variables with more than two possible choices	Smoking status	Based on the Chi-squared test. It is possible to calculate the p-value only if the expected frequencies for each choice both in the population and in the cohort is equal to or greater than one and if less than 20% of expected frequencies are equal to or less than five.
Survival variables	Progression free survival or Overall survival	Based on the Log-rank test. It is possible to calculate the p-value only if each group includes at least one patient.

| Table 3 P-value calculation for different types of variables

### 9 Information and support

SOPHiA CarePath provides supporting information, to help you get the best out of your SOPHiA GENETICS applications.

To access the supporting information, from the bottom-left of any view, select ?. The *Contact Us & Documentation* option menu opens, which contains the following information and functions:

- The SOPHiA CarePath software version
- · The cohorting dataset version
- Access to legal documentation
- Contact us opens the Contact us dialog, which lists the SOPHiA GENETICS email address, phone numbers, and website
- Download documentation downloads the SOPHiA CarePath manual PDF



When you contact our support team by email, please use your login email address, specify the product name (e.g. SOPHiA CarePath) and include any relevant information to help us solve your issue.

# 10 Operating instructions

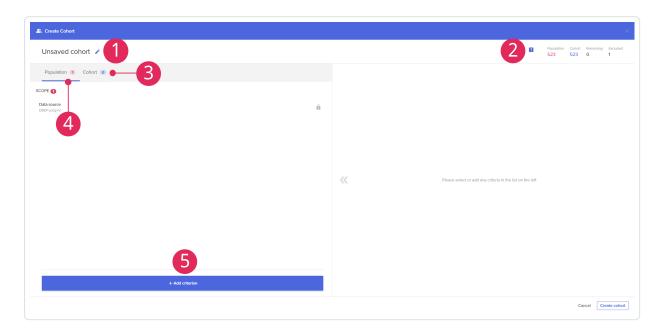
This section describes the actions that can be performed in SOPHiA CarePath.

### 10.1 Create a cohort

SOPHiA CarePath allows you to determine the outcome of a group of patients that correspond to a specific patient profile by creating a cohort. When creating a cohort, you must first define a group of patients. This group is called a Population and will be the initial patient pool from which you will define a tailored cohort. By defining the Population and then the Cohort, you can compare the outcome of the cohort with the group of Remaining patients. Remaining patients are patients from the Population group that are not included in the cohort.

#### To create a cohort:

1. From the homepage, select the **New cohort** button or, from the **Cohort list** view, select **t**. The **Create cohort** wizard opens.



Number	Description		
1	Edit button - allows you to change the name and description of the cohort.		
2	Patient count - displays the number of patients included and excluded from the cohort, based on the applied criteria. For more information on patient count, refer to "Cohort detail view" on page 21.		
3	Cohort tab - open this tab to view the selected cohort criteria. The number shows the number of selected cohort criteria.		
4	<b>Population</b> tab - open this tab to view the selected population criteria. The number shows the number of selected population criteria.		
5	Add criterion button - opens a list of criteria that you can add to the population or the cohort.		

| Figure 5: Create cohort wizard



Before you add any criteria, all patients from the dataset are included in the population and added by default to the cohort group, except patients for which one or several clinical outcomes (PFS, OS, clinical response at 1st evaluation) are missing.

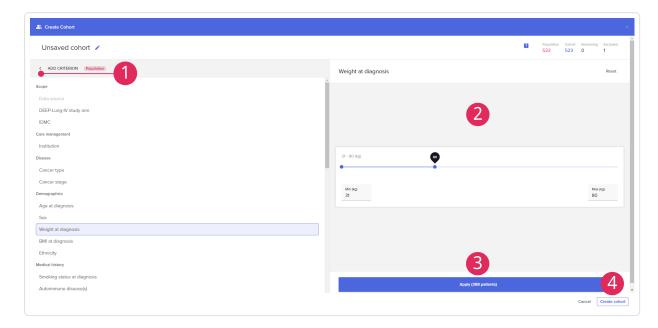


The study criteria is added by default to the population and configured to include patients from the Deep-Lung-IV study as for now only patient from this study are part of the dataset. This criteria can't be modified or deleted.

- 2. Select the type of criteria you want to add:
  - To add population criteria, select the *Population* tab.
  - To add cohort criteria, select the *Cohort* tab.
  - For more information about populations and cohorts, refer to "Cohort detail view" on page 21.
- 3. Select Add criterion.

4. Select a criterion from the criteria list.

Settings for that criterion are displayed on the right.



Number	Description	
1	Back button - takes you back to the population and cohort criteria lists.	
2	Criteria settings - allows you to configure the settings of the selected criteria.	
3	<b>Apply</b> button - indicates the number of patients that match the selected population or cohort criterion and settings, including all previously applied criteria. Selecting <b>Apply</b> applies the criteria and settings to the cohort.	
4	Create cohort button - creates the cohort based on the applied criteria.	

| Figure 6: Create cohort wizard - cohort criterion settings

5. Select the settings you want to add.



The count on the *Apply* button indicates the number of patients that match the selected population or cohort criterion and settings, including all previously applied criteria.

### 6. Select Apply.

The selected criterion and settings are added to the cohort or population. You can select as many criteria and settings as you need.



When the defined criteria lead to *Cohort* and *Remain* groups with very small numbers of patients, the cohort result will be poorly statistically relevant.



When a cohort or population criterion is selected, the patients for which the criteria is unknown are removed from the population and added to the excluded group.



When population criteria settings are defined, the patients from the dataset that do not correspond to the population criteria are removed from the population group and from the cohort or remaining group depending on which they were associated before.



When cohort criteria settings are defined, the patient from the population that correspond to the cohort criteria are added to the cohort group and the other to the remaining group.

#### Select Create cohort.



To prevent patient identification, you cannot create a cohort with a single patient in the cohort or the remaining group.

8. If you have not modified the name and description at an earlier stage, enter the following details:



Do not use personally identifiable information in the cohort name or description.

Cohort name (mandatory)



The cohort name must be unique in your institution account, fewer than 55 characters and contain only alphanumeric characters, space dashes and underscores.

Description (optional)



The description is limited to 200 characters. It is visible on cards in the **Cohort** list view, and in the **Cohort** detail view, by hovering over the description icon in the cohort banner.

#### 9. Select Save.

The cohort is created and added to the *Cohort* list view.

The *Cohort* detail view opens.

### 10.2 View a cohort

You can view the cohorts you created in the *Cohort* list view.

To view a cohort:

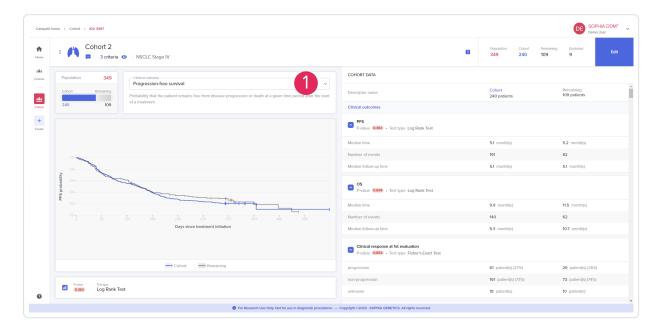
- 1. From the navigation bar on any view, select 2.
  - The *Cohort* list view opens.
- 2. Select the name of the cohort that you want to view.
  - The *Cohort* detail view opens.

### 10.2.1 Switch views of the Clinical outcome graph

The clinical outcome graph in the *Cohort* detail view displays data for different types of clinical outcome. You can switch the view of the graph to see data for each outcome.

To switch the view of the *Clinical outcome* graph:

- From the *Clinical outcome* drop-down, select one of the following outcomes:
  - Progression-free survival
  - Overall survival
  - Clinical response at 1st evaluation



Number Description

Clinical outcome drop-down

| Figure 7: Clinical outcome drop-down

► For more information, refer to <u>"Cohort detail view" on page 21</u>.

### 10.3 Delete a cohort

You can delete cohorts in the *Cohort* list view.



When you delete a cohort, it is permanently deleted and cannot be recovered.

#### To delete a cohort:

- 1. From the navigation bar on any view, select 🕰.
  - The *Cohort* list view opens.
- 2. For the cohort you want to delete, select .
- 3. Select Delete.
  - A confirmation dialog opens.
- 4. In the text field, enter DELETE.
- 5. Select Delete.

### 10.4 Edit a cohort

You can edit the name, population criteria, cohort criteria and the criteria settings for a cohort.

#### To edit a cohort:

1. From the navigation bar on any view, select 2.

The *Cohort* list view opens.

2. Select the name of the cohort that you want to edit.

The Cohort detail view opens.

3. Select Edit.

The *Edit cohort* wizard opens.

- 4. To change the cohort name and description, do the following:
  - a. Next to the cohort name, select .
  - b. Change the name and description.
  - c. Select *Save*.
- 5. To add new criteria, do the following:
  - a. Select the type of criteria you want to add:
    - · To add population criteria, select the *Population* tab.
    - To add cohort criteria, select the *Cohort* tab.
    - For more information about populations and cohorts, refer to "Cohort detail view" on page 21.
  - b. Select Add criterion.

- c. Select a criterion from the criteria list.
  - Settings for that criterion are displayed on the right.
- d. Select the settings you want to add.
- e. Select Apply.
- 6. To change the parameters of criteria, do the following:
  - a. Select the type of criteria you want to change the parameters for:
    - · To change the parameters for population criteria, select the *Population* tab.
    - To change the parameters for cohort criteria, select the *Cohort* tab.
  - b. Select the criterion from the criteria list.

Settings for that criterion are displayed on the right.

- c. Change the settings.
- d. Select Apply.
- 7. To delete criteria, do the following:
  - a. Select the type of criteria you want to delete:
    - · To delete population criteria, select *Population*.
    - To delete cohort criteria, select Cohort.
  - b. For the criterion you want to delete, select
  - c. Select Confirm delete.
- 8. Select Save and close.

### 10.5 Duplicate a cohort

You can duplicate an existing cohort to save time when creating similar cohorts.

To duplicate a cohort:

1. From the navigation bar on any view, select 2.

The **Cohort** list view opens.

- 2. For the cohort you want to duplicate, select .
- 3. Select Duplicate.

The Create cohort wizard opens with all details populated based on the original cohort.

- 4. Next to the cohort name, select
- 5. Change the name and description.
- 6. Select Save.



To ensure a unique name for each cohort, reuse of the original name is not allowed.

- 7. Add new criteria.
  - ► For more information, refer to <u>"Edit a cohort" on page 33</u>.
- 8. Select Create cohort.

### 10.6 Bookmark a cohort

In the *Cohort* list view, you can bookmark cohorts for quicker access.

To bookmark a cohort:

- From the navigation bar on any view, select .
   The Cohort list view opens.
- 2. On the cohort card you want to bookmark, select

To remove a bookmark:

- From the navigation bar on any view, select ...
   The Cohort list view opens.
- 2. On the cohort card you want to remove the bookmark from, select \_\_\_\_.

## 11 Disposal information

There is no disposal information for SOPHiA CarePath.

## 12 Maintenance

There are no maintenance requirements for SOPHiA CarePath.

# 13 Troubleshooting

There are no troubleshooting requirements for SOPHiA CarePath.

## 14 Support information

SOPHiA GENETICS

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CH-1180 Rolle, Switzerland

European Union: +41 21 561 34 75

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United States: +1 617 313 7957

 $\label{lem:bound} \begin{tabular}{ll} Email: $\underline{$support@sophiagenetics.com}$ \\ Website: $\underline{www.sophiagenetics.com}$ \\ \end{tabular}$ 

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