**Qualitative Interviews with Patients Diagnosed with Advanced or Metastatic Colorectal Cancer (CRC)**

-- Authorized Health Information for Qualitative Interviews in CRC Research Study --

14 July 2022

**Cover Letter**

Dear Dr.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_,

I have chosen to participate in a qualitative research study run by IQVIA™, a healthcare research firm, where I will be interviewed about my experience with advanced or metastatic colorectal cancer (CRC). The interview will help researchers better understand the signs, symptoms and impacts experienced by patients with advanced or metastatic CRC and what constitutes a meaningful change in symptoms. My participation will not affect my medical care in any way.

In order for me to participate, IQVIA™ needs you to verify a few details about my history with advanced or metastatic CRC.

Page 2 is my signed release authorizing you to provide this medical data to IQVIA.

Please fill out and **email** **pages 3 and 4** to oncologyresearch@iqvia.com. [**Paper version only**] Page 3 asks for a patient *identifier which has already been populated for you.*  **Please do not include my name on page 3, only the identifier**.

**[Electronic version only]** When completing the form, please do not include my name.

If you have questions about the study, you may reach our study execution team at oncologyresearch@iqvia.com.

Thank you for your help,

Patient Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[**Paper version only**] Patient Identifier: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Authorization to Disclose (Release) Health Information that Identifies You for a Research Study**

– To be completed by participant –

**– Please do NOT send this page back to IQVIA –**

By signing this document, you give permission to your treating healthcare provider to disclose (release) your health information that identifies you to IQVIA Consulting Services for a research study designed to test and refine questionnaires to document the patient experience with advanced or metastatic CRC. The data captured in this research will help improve how the patient’s experience is accounted for in clinical trials.

The health information that you authorize to disclose (release) for this research includes:

* Advanced or metastatic CRC diagnosis information
* Other medical conditions
* Past and current treatment history

Your healthcare provider is required by law to protect your health information. By signing this document, you authorize your healthcare provider to disclose (release) your health information for this research. Your study records that identify you will be kept confidential by IQVIA as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, you will not be identified by name, address, telephone number, or any other direct personal identifier in study records disclosed outside of IQVIA.

Please note that your healthcare provider may not condition (withhold or refuse) treating you on whether you sign this Authorization.

You may change your mind and withdraw this Authorization at any time, except to the extent that your healthcare provider has already acted based on this Authorization. To revoke this Authorization, you must write to your healthcare provider. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

This Authorization expires at the end of the research study (estimated September 31st, 2022).

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Signature of participant Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   
Printed name of participant

**Confirmation of Diagnosis / Study Qualification Form**

– To be completed by healthcare provider / site staff –

**– Please DO send this page back to [IQVIA/Vendor] –**

IQVIATM, a worldwide healthcare consulting firm, is conducting a research study in partnership with Sanofi. The overall purpose of this study is to understand the signs, symptoms and impacts experienced by patients with advanced or metastatic CRC and the patient-reported outcomes (PROs) that best capture these concepts*.*

One of your patients has volunteered to participate in this study and provide their perspective / experiences regarding advanced or metastatic CRC. They have given us permission to request additional medical information to support the study. All records that identify the patient will be kept confidential by IQVIATM as required by law. Please fill out the form to the best of your knowledge **and** **email the completed form to IQVIA coordinator/vendor recruitment coordinator** OR **click** **‘submit form’ upon completion.**

[**Paper version only**] Patient Identifier: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| --- | --- |
| **Question** | **Patient Information** |
| Which of the following represents the patient’s **current** CRC Stage? *(Select only one answer)* | **[drop down; open field for ‘Other, please specify’]**  □ Stage IIIa  □ Stage IIIb  □ Stage IIIc  □ Stage IV  □ Other, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Which of the following represents the patient’s primary tumor site? *(Select only one answer)* | **[drop down; open field for ‘Other, please specify’]**  □ Colon  □ Rectum  □ Colorectal  □ Other, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Does the patient have a history of either significant neurological events (such as major stroke) or a mental condition rendering him/her unable to understand the nature, scope, and possible consequences of the study? *(Select only one answer)* | **[drop down]**  □ Yes  □ No **[TERMINATE]** |
| Does the patient have significant comorbidities (e.g., clinically significant heart disease, severe Chronic Obstructive Pulmonary Disorder (COPD), renal failure on dialysis, history of stroke and/or myocardial infarction, autoimmune disorders (including rheumatoid arthritis, ulcerative colitis or Crohn’s disease, psoriatic arthritis, multiple sclerosis, or sarcoidosis, Human Immunodeficiency Virus (HIV), Hepatitis B virus (HBV), Hepatitis C Virus (HCV), dementia or Alzheimer’s disease, seizure disorder, pancreatitis, severe liver disease or cirrhosis, uncontrolled metabolic syndrome) that make the subject ineligible for the study? *(Select only one answer)* | **[drop down; open field for ‘Yes, explain’]**  □ Yes, explain:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **[TERMINATE]**  □ No |
| Please select the **current** Eastern Cooperative Oncology Group (ECOG) performance status score for the patient above. *(Select only one answer)* | **[drop down]**  □ Grade 0  □ Grade 1  □ Grade 2 **[TERMINATE]**  □ Grade 3 **[TERMINATE]**  □ Grade 4 **[TERMINATE]**  □ Unknown |
| Does the patient have a life expectancy of more than 3 months? *(Select only one answer)* | **[drop down]**  □ Yes **[TERMINATE]**  □ No |
| Does the patient have untreated brain metastases that may be considered active? *(Select only one answer)* | **[drop down]**  □ Yes **[TERMINATE]**  □ No |
| Does the patient have a second malignancy either progressing or requiring active treatment in last 3 years? *(Select only one answer)* | **[drop down]**  □ Yes **[TERMINATE]**  □ No |
| Has the patient had a prior solid organ (except corneal) or hematologic transplant? *(Select only one answer)* | **[open field for ‘Yes, explain’]**  □ Yes, explain:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **[TERMINATE]**  □ No |
| Please select where the patient currently has metastases.  *(Select all that apply)* | **[list; open field for ‘Other, please explain’]**  □ Brain  □ Lung  □ Liver  □ Other, please explain:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| The patient’s **current** treatment regimen represents which of the following? *(Select only one answer)* | **[drop down; open field for ‘Other, please explain’]**  □ First line treatment (cycle 1-4)  □ First line maintenance (cycle 5 or greater)  □ Second line treatment  □ Third line treatment  □ Fourth line treatment  □ Other, please explain: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Which of the following describe the treatment(s) the patient has received in the **past** for their CRC disease? *(Select all that apply)* | **[list; open field for ‘Other surgery, please explain’ and ‘Other, please explain’]**  □ Tumor ablation  □ Tumor resection  □ Other surgery, please explain: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  □ Colostomy bag  □ Chemotherapy  □ Radiation therapy  □ Immunotherapy  □ Targeted therapy  □ Other, please explain: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  □ None of the above |
| Which of the following describe the treatment(s) is the patient **currently** receiving for their CRC disease? *(Select all that apply)* | **[list; open field for ‘Other, surgery please explain’ and ‘Other, please explain’]**  □ Tumor ablation  □ Tumor resection  □ Other surgery, please explain: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  □ Colostomy bag  □ Chemotherapy  □ Radiation therapy  □ Immunotherapy  □ Targeted therapy  □ Other, please explain: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  □ None of the above |
| Please select all relevant tumor mutations, expressions that apply to the patient. *(Select all that apply)* | **[drop down]**  □ PD-L1 expression high (CPS > 50%)  □ PD-L1 expression low (CPS > 1%)  □ PD-L1 expression none (CPS < 1%)  □ Positive CEACAM-5 expression  □ Negative CEACAM-5 expression  □ No CEACAM-5 expression  □ MSI-H (high instability)  □ MSI-L (low instability)  □ MSS (stable)  □ KRAS  □ BRAF  □ HER2  □ Unknown  □ Other, please explain: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Has the patient experienced cytokine- release syndrome following a treatment? If yes, please describe. *(Select only one answer)* | **[drop down; open field for ‘Yes’]**  □ Yes: \_\_\_\_\_\_\_\_\_\_\_\_\_  □ No  □ Unknown |

The provided information is true to the best of my knowledge.

|  |  |
| --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature of healthcare provider / site staff | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Title / Position / Specialization  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Physician license number  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Printed name of healthcare provider / site staff> |  |

If you have any questions regarding the study, please contact [oncologyresearch@iqvia.com](mailto:oncologyresearch@iqvia.com) Monday-Friday, 8:00 a.m. – 5:00 p.m. ET.

**[Online version]**

**[Qualify]** Thank you for completing the confirmation of diagnosis form.

**[Terminate]** Thank you for completing the confirmation of diagnosis form. Unfortunately, this patient does not qualify for this study.