PFIZER

Pfizer-BioNTech COVID-19 Vaccine, also known as COMIRNATY® IVR & Live Operator Script Greetings

PP-CVV-USA-0378

877-829-2619 (877-VAX-CO19)

Topic			Script Verbiage and Logic
1.0 Live Operator Script Welcome for PP-CVV-USA-0303			

1.0	Welcome	1.1	Good (Morning/Afternoon/Evening) and thank you for calling the customer service center for the Pfizer-BioNTech COVID-19 vaccine, also known as COMIRNATY® (COVID-19 Vaccine, mRNA)*.
			
			*The licensed COMIRNATY® vaccine has the same formulation as the authorized vaccine Pfizer-BioNTech Covid-19 Vaccine, and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct, with certain differences that do not impact safety or effectiveness.
			
			My name is____. How may I help you today?
			
			Before we continue, I need to share the following important safety information with you…
			
			COMIRNATY® (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech.
			
			• It is approved as a 2-dose series for prevention of COVID-19 in individuals 16 years of age and older
			• It is also authorized under Emergency Use Authorization (EUA) to be administered for emergency use to:
			  ○ prevent COVID-19 in individuals 12 through 15 years, and
			  ○ provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
			
			The Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA to:
			• prevent COVID-19 in individuals 12 years of age and older, and
			• provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
			
			The FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series. An individual may be offered either COMIRNATY® (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2.
			
			The emergency use of the product has not been approved or licensed by FDA, but has been authorized by FDA, under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 12 years of age and older; and the emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

This is an update to PP-CVV-USA-0303, Section 1.0 Greeting. Only the updated section has been submitted. Please see live operator map on page 7 for a detailed explanation of the section that has been updated and PP-CVV-USA-0303 for the remaining pages. PP-CVV-USA-0303 has been submitted to CBER with copy to APLB on 08/04/2021

			You should **not** get the Pfizer-BioNTech COVID-19 Vaccine if you: • had a severe allergic reaction after a previous dose of this vaccine • had a severe allergic reaction to any ingredient of this vaccine Tell the vaccination provider about all of your medical conditions, including if you: • have any allergies • have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart) • have a fever • have a bleeding disorder or are on a blood thinner • are immunocompromised or are on a medicine that affects your immune system • are pregnant, plan to become pregnant, or are breastfeeding • have received another COVID-19 vaccine • have ever fainted in association with an injection The vaccine may not protect everyone. Side effects reported with the vaccine include: There is a remote chance that the vaccine could cause a severe allergic reaction • A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination ▪ Signs of a severe allergic reaction can include difficulty breathing, swelling of your face and throat, a fast heartbeat, a bad rash all over your body, dizziness, and weakness ▪ If you experience a severe allergic reaction, call 9-1-1 or go to the nearest hospital • Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the vaccine. In most of these people, symptoms began within a few days following receipt of the second dose of the vaccine. The chance of having this occur is very low. You should seek medical attention right away if you have any of the following symptoms after receiving the vaccine: ▪ chest pain

- shortness of breath
- feelings of having a fast-beating, fluttering, or pounding heart

- Side effects that have been reported with the vaccine include:
  - severe allergic reactions; non-severe allergic reactions such as rash,itching, hives, or swelling of the face; myocarditis (inflammation of the heart muscle); pericarditis (inflammation of the lining outside the heart); injection site pain; tiredness; headache; muscle pain; chills; joint pain; fever; injection site swelling; injection site redness; nausea; feeling unwell; swollen lymph nodes (lymphadenopathy); diarrhea; vomiting; arm pain

- These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The vaccine is still being studied in clinical trials. Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away

There is no information on the use of this vaccine with other vaccines.

Patients should always ask their healthcare providers for medical advice about adverse events. Report negative side effects of vaccines to the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Visit http://www.vaers.hhs.gov or call 1-800-822-7967. In addition, you can report side effects to Pfizer Inc. at www.pfizersafetyreporting.com or by calling 1-800-438-1985.

Please visit www.comirnaty.com for full Prescribing Information (16+ years of age) and Recipient and Caregiver Fact Sheet (12+ years of age).

PP-CVV-USA-0378-01

1.0 IVR Script Welcome for PP-CVV-USA-0304
1.1 Welcome Transfers from Pfizer Trade IVR for PP-CVV-USA-0304

1.0 **1. 1**	**Welcome**	This is an update to PP-CVV-USA-0304, Section 1.0 Welcome and Section 1.1 Welcome Transfers from Pfizer Trade IVR. Only the updated sections have been submitted. Please see IVR map on page 8 for a detailed explanation of the section that has been updated and PP-CVV-USA-0304 for the remaining pages. PP-CVV-USA-0304 has been submitted to CBER with copy to APLB on 08/04/2021	Thank you for calling the customer service center for the Pfizer-BioNTech COVID-19 Vaccine, also known as COMIRNATY® (COVID-19 Vaccine, mRNA)*. *The licensed COMIRNATY® vaccine has the same formulation as the authorized vaccine Pfizer-BioNTech Covid-19 Vaccine, and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct, with certain differences that do not impact safety or effectiveness. Before we continue, I need to share the following important safety information with you… COMIRNATY® (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech. • It is approved as a 2-dose series for prevention of COVID-19 in individuals 16 years of age and older • It is also authorized under Emergency Use Authorization (EUA) to be administered for emergency use to: ▪ prevent COVID-19 in individuals 12 through 15 years, and ▪ provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise The Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA to: • prevent COVID-19 in individuals 12 years of age and older, and • provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise The FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series. An individual may be offered either COMIRNATY® (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2. The emergency use of the product has not been approved or licensed by FDA, but has been authorized by FDA, under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 12 years of age and older; and the emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

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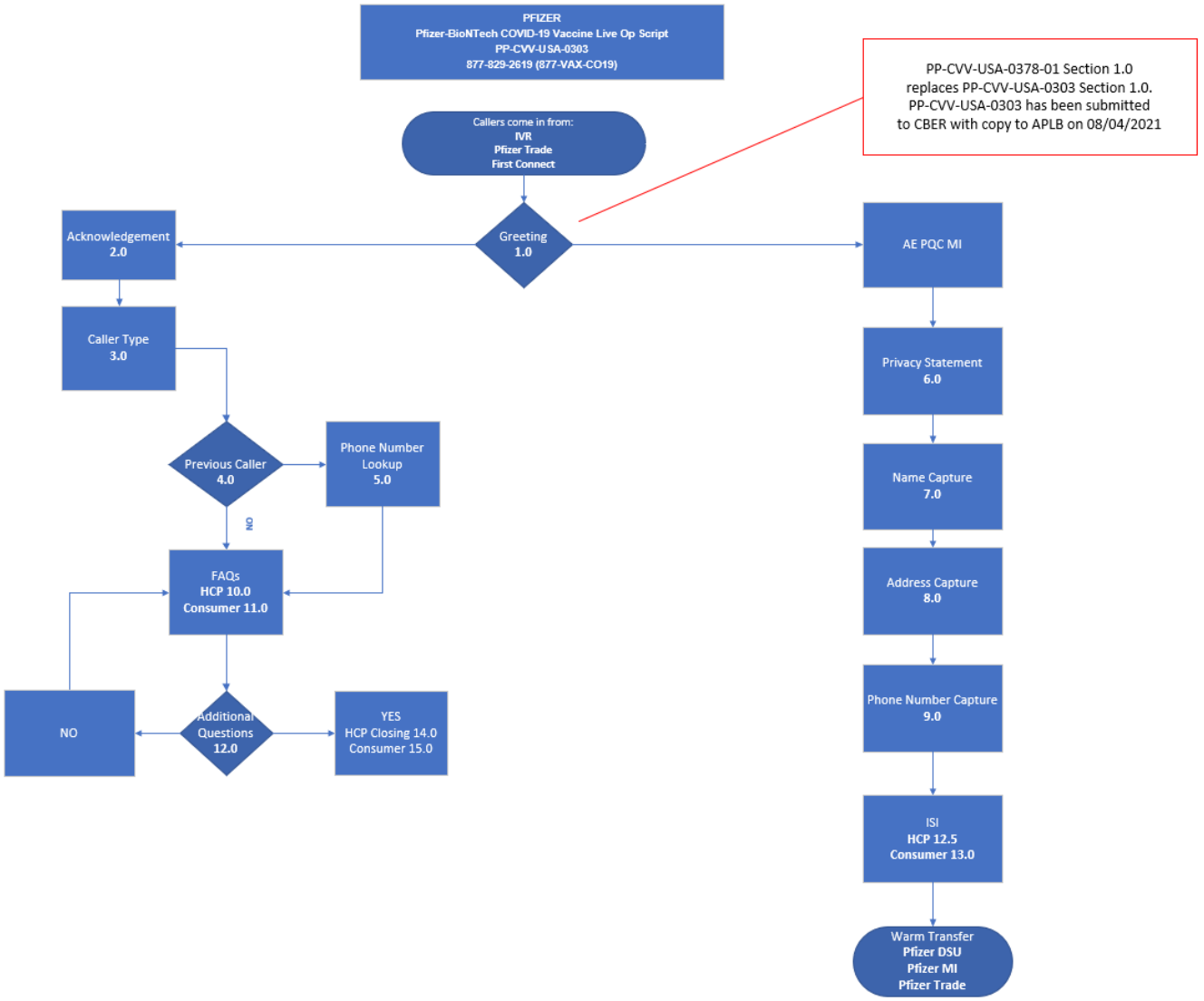
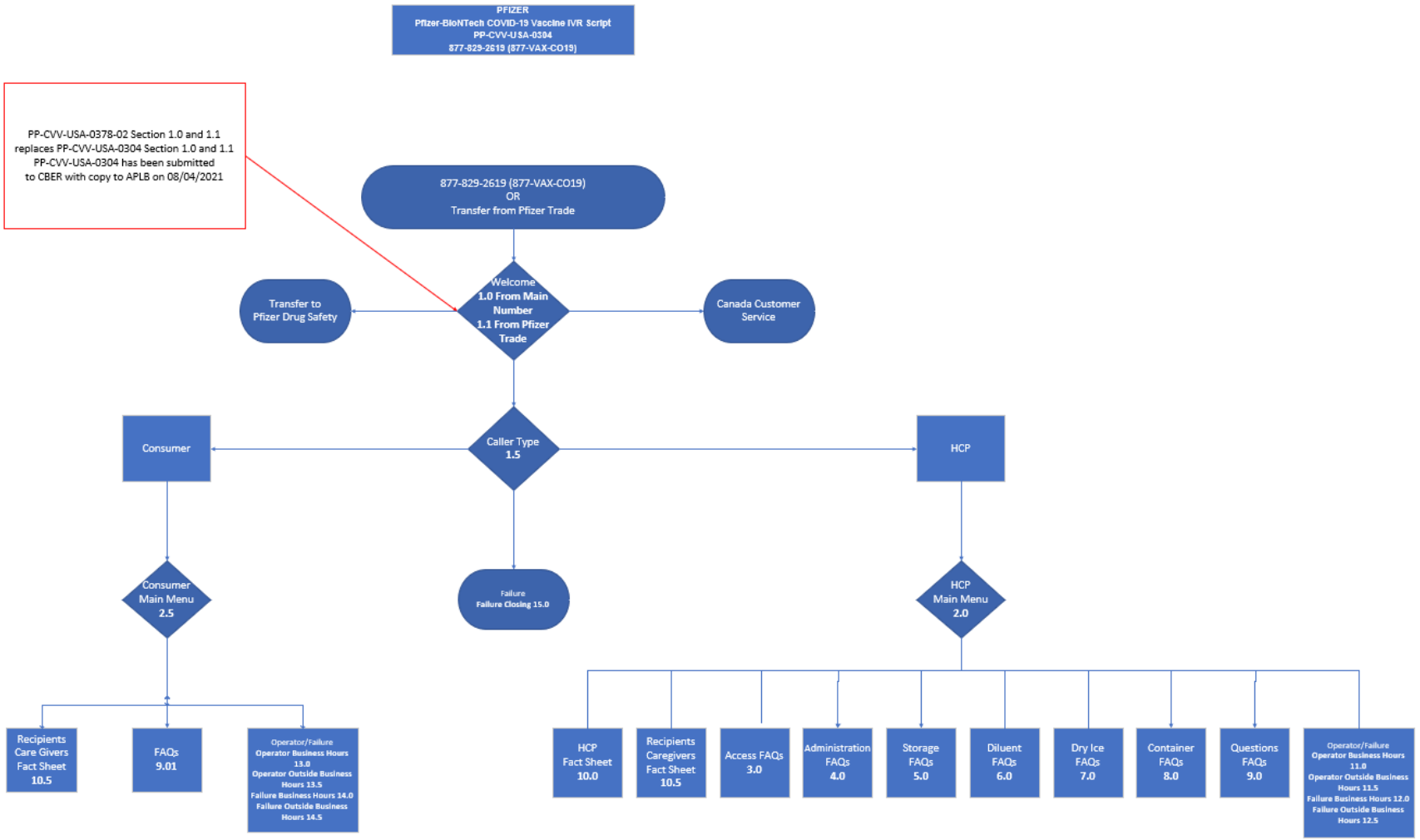
			▪ shortness of breath ▪ feelings of having a fast-beating, fluttering, or pounding heart • Side effects that have been reported with the vaccine include: ▪ severe allergic reactions; non-severe allergic reactions such as rash, itching, hives, or swelling of the face; myocarditis (inflammation of the heart muscle); pericarditis (inflammation of the lining outside the heart); injection site pain; tiredness; headache; muscle pain; chills; joint pain; fever; injection site swelling; injection site redness; nausea; feeling unwell; swollen lymph nodes (lymphadenopathy); diarrhea; vomiting; arm pain. • These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The vaccine is still being studied in clinical trials. Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away There is no information on the use of this vaccine with other vaccines. Patients should always ask their healthcare providers for medical advice about adverse events. Report negative side effects of vaccines to the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Visit http://www.vaers.hhs.gov or call 1-800-822-7967. In addition, you can report side effects to Pfizer Inc. at www.pfizersafetyreporting.com or by calling 1-800-438-1985. Please visit www.comirnaty.com for full Prescribing Information (16+ years of age) and Recipient and Caregiver Fact Sheet (12+ years of age). PP-CVV-USA-0378-02


PFIZER
Pfizer-BioNTech COVID-19 Vaccine Live Op Script
PP-CVV-USA-0303
877-829-2619 (877-VAX-CO19)
PP-CVV-USA-0378-01 Section 1.0
replaces PP-CVV-USA-0303 Section 1.0.
PP-CVV-USA-0303 has been submitted
to CBER with copy to APLB on 08/04/2021
Callers come in from:
IVR
Pfizer Trade
First Connect
Greeting
1.0
Acknowledgement
2.0
AE PQC MI
Caller Type
3.0
Privacy Statement
6.0
Previous Caller
4.0
Phone Number
Lookup
5.0
NO
Name Capture
7.0
FAQs
HCP 10.0
Consumer 11.0
Address Capture
8.0
Phone Number Capture
9.0
NO
Additional
Questions
12.0
YES
HCP Closing 14.0
Consumer 15.0
ISI
HCP 12.5
Consumer 13.0
Warm Transfer
Pfizer DSU
Pfizer MI
Pfizer Trade


PFIZER
Pfizer-BioNTech COVID-19 Vaccine IVR Script
PP-CVV-USA-0304
877-829-2619 (877-VAX-CO19)
PP-CVV-USA-0378-02 Section 1.0 and 1.1 replaces PP-CVV-USA-0304 Section 1.0 and 1.1 PP-CVV-USA-0304 has been submitted to CBER with copy to APLB on 08/04/2021
877-829-2619 (877-VAX-CO19) OR Transfer from Pfizer Trade
Welcome 1.0 From Main Number 1.1 From Pfizer Trade
Transfer to Pfizer Drug Safety
Canada Customer Service
Caller Type 1.5
Consumer
HCP
Consumer Main Menu 2.5
Failure Failure Closing 15.0
HCP Main Menu 2.0
Recipients Care Givers Fact Sheet 10.5
FAQs 9.01
Operator/Failure Operator Business Hours 13.0 Operator Outside Business Hours 13.5 Failure Business Hours 14.0 Failure Outside Business Hours 14.5
HCP Fact Sheet 10.0
Recipients Caregivers Fact Sheet 10.5
Access FAQs 3.0
Administration FAQs 4.0
Storage FAQs 5.0
Diluent FAQs 6.0
Dry Ice FAQs 7.0
Container FAQs 8.0
Questions FAQs 9.0
Operator/Failure Operator Business Hours 11.0 Operator Outside Business Hours 11.5 Failure Business Hours 12.0 Failure Outside Business Hours 12.5