UI Designs & Concepts

CCP-TAP Webform with PRA Considerations

Objective

Create a webform for sponsors to request TAP enrollment.

Requirements

- Display the required **PRA language on the first "page"**:
  - "OMB Control No. 0910-NEW"
  - "Expiration date: tbd"
  - The following PRA statement (which may be placed with a text box to help distinguish it from other info, but it doesn't have to be):
    - According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0910-NEW. The time required to complete this information collection is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

      Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden to PRAStaff@fda.hhs.gov.

Request to enroll in the TAP Pilot

OMB Control No.0910-NEW | Expiration date: tbd | Refer to the PRA Statement for details.
Send your request before 16:00 ET on a business day for us to process it the same day.
Fields are required unless noted as (optional).

Basic qualifications — Device & sponsor information — Review & send to FDA

Basic qualifications

1. **Has your proposed device been granted a Breakthrough designation?** https://www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program
   - ○ Yes (answer for TAP acceptance)
   - ○ No

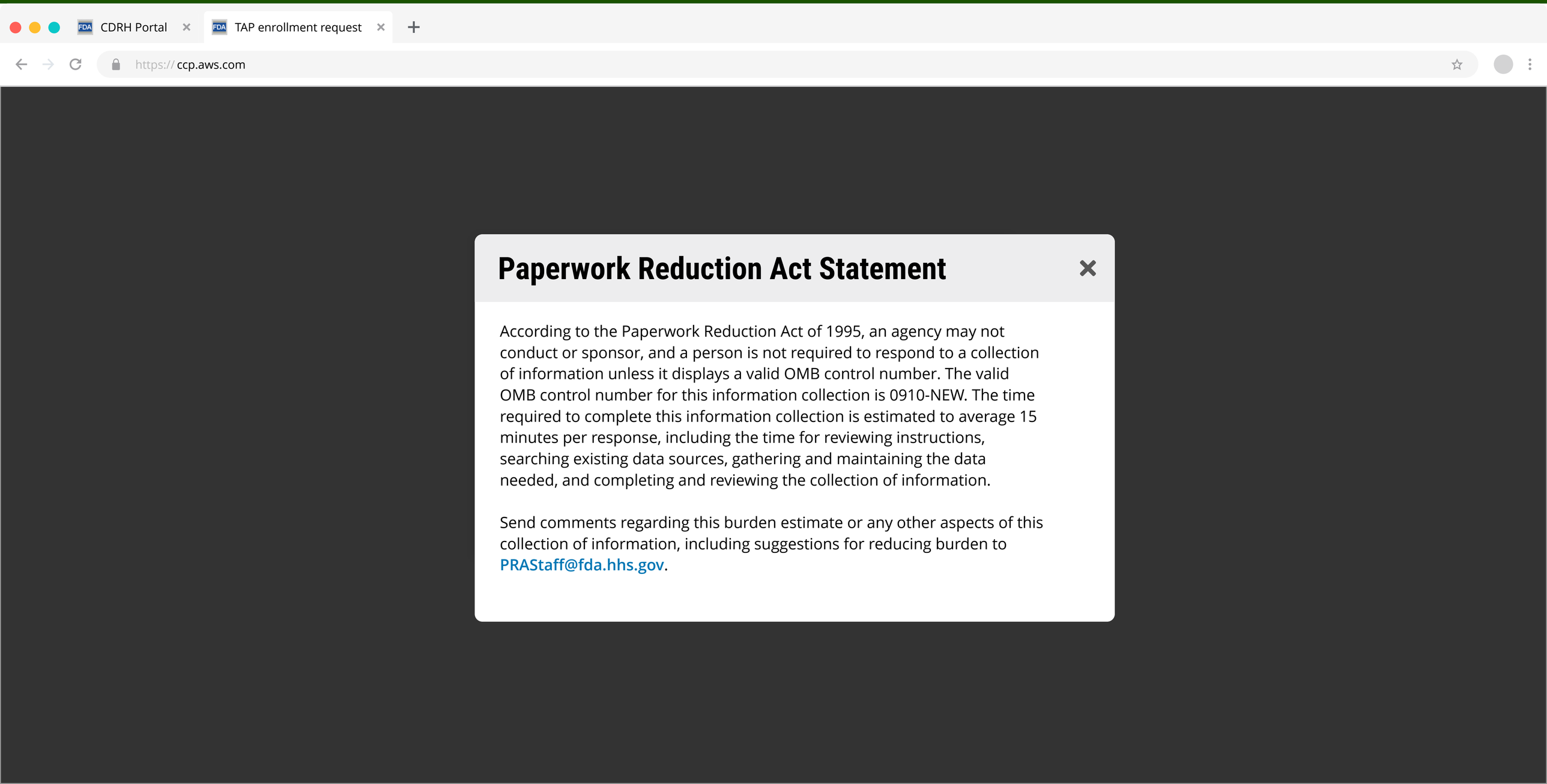
2. **Have you submitted and received feedback through a Pre-Submission about your device after being granted a Breakthrough designation?** https://www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program
   - ○ Yes
   - ○ No (answer for TAP acceptance)

3. **Is your device early in its device development process (e.g., a pivotal study has not yet been initiated for the device) at the time of enrollment?**
   - ○ Yes (answer for TAP acceptance)
   - ○ No

4. **Do you already have a device enrolled in the TAP Pilot for the current fiscal year (October 1 - September 30)?** https://www.fda.gov/medical-devices/how-study-and-market-your-device/total-product-life-cycle-advisory-program-tap
   - ○ Yes
   - ○ No (answer for TAP acceptance)

5. **Is your device regulated by the Center for Biologics Evaluation and Research (CBER) or regulated as a combination product?** https://www.fda.gov/combination-products
   - ○ Yes
   - ○ No (answer for TAP acceptance)

Cancel request | Save | Next


CDRH Portal
TAP enrollment request
https:// ccp.aws.com
Paperwork Reduction Act Statement
According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0910-NEW. The time required to complete this information collection is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.
Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden to PRAStaff@fda.hhs.gov.

CDRH Portal | TAP enrollment request

https:// ccp.fda.gov/prweb/PRAuth/app/default/extsso

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Basic qualifications — **Device & sponsor information** — Review & send to FDA

Device & sponsor information

Device information

Q-Submission number

Provide the Q-Submission number under which your device was granted a Breakthrough Device designation.

Q123456

Product name

Blood Pressure Cuff

Sponsor information

Company name

MedInnovate Solutions Inc.

Address line 1

123 Health Way

Address line 2 (optional)

Suite 456

City

MedTech City

State (US)

MD

ZIP/Postal code

78901

Country

United States

Province/region (optional)

Business phone number (optional)

+1-234-432-4224

Website URL (optional)

https://www.medinnovatesolutions.com

Primary point of contact

First name

Paula

Last name

Bennett

Title (optional)

Regulatory Affairs Specialist

Phone number

+1-222-222-2222

Email address

paula.bennett@mis.com

Cancel request

Save Next

Request to enroll in the TAP Pilot

OMB Control No.0910-NEW | Expiration date: tbd | Refer to the PRA Statement for details.

Send your request before 16:00 ET on a business day for us to process it the same day.

Fields are required unless noted as (optional).

Basic qualifications — Device & sponsor information — **Review & send to FDA**

Review & send to FDA

The information you entered is shown below. Select the pencil icon to edit it.

Basic qualifications

1. **Has your proposed device been granted a Breakthrough designation?**
   Yes

2. **Have you submitted and received feedback through a Pre-Submission about your device after being granted a Breakthrough designation?**
   No

3. **Is your device early in its device development process (e.g., a pivotal study has not yet been initiated for the device) at the time of enrollment?**
   Yes

4. **Do you already have a device enrolled in the TAP Pilot for the current fiscal year (October 1 - September 30)?**
   No

5. **Is your device regulated by the Center for Biologics Evaluation and Research (CBER) or regulated as a combination product?**
   No

Device & sponsor information

Device information

Q-Submission number
Q9999999

Product / Trade Name
Blood Pressure Cuff

Sponsor information

Company name
MedInnovate Solutions Inc.

Address
123 Health Way
Suite 456
MedTech City, MD 7901
United States

Business phone number
+1-234-432-4224

Website URL
https://www.medinnovatesolutions.com

Point(s) of Contact
Paula Bennett (primary)
Regulatory Affairs Specialist
+1-222-222-2222
paula.bennett@mis.com

Cancel request | Save | Send

Sent to FDA

You have sent your TAP enrollment request TPR-2024-000000. (Sent on Feb 2, 20XX at 17:10 ET).

We will send an enrollment status update within 30 business days. This does not guarantee an acceptance. Thank you for your interest in the TAP Pilot.

Contact TPLC-Advisory-Program@fda.hhs.gov if you have any questions or feedback.

You can see the status of your request on the home page once it has been refreshed.

You may close this browser tab.