Competent Authorities for Medical Devices (CAMD) project

Specification for the development of a website

1. Introduction

The European Union (EU) CAMD project was established in 2014 to enhance collaborative working, communication and surveillance of medical devices across Europe. This was an outcome of the Dalli Plan for Joint Action, initiated by Commissioner John Dalli in the aftermath of the breast implant scandal in 2012.

The CAMD network is an umbrella under which the national competent authorities in the EU, and associated parties to the system (European Free Trade Association (EFTA) and Turkey), work to enhance the level of collaborative work in what is a single market for medical devices.

Competent authorities have specific responsibilities for market surveillance and other activity under the terms of the legislation. The governance for the network was changed in 2014 to incorporate an elected executive. The executive was charged with developing better collaboration with the European Commission to improve both strategic planning and the distribution of work across both Commission-led and CAMD-led working groups.

The Dalli plan set out three challenges: enhance collaborative working; improve market surveillance; and better communication. Subsequently, the CAMD network has initiated two Joint Action projects which are designed to help the member states deliver on these commitments, and develop better mechanisms for working together and sharing workload:

- The first concerns the quality of instructions for use of re-sterilisable surgical instruments and is led by the Austria competent authority. This started in November 2015 and is due to be completed by December 2017.

- The second concerns market surveillance of medical devices which is more expansive and led by the UK competent authority (Medicines and Healthcare products Regulatory Agency). This, subject to agreement, will run from autumn 2016 to autumn 2019.

The CAMD is aiming to have a substantial impact by:

- Enhancing patient safety by improving collaborative work across the EU medical devices network

- Specifically address key elements of recognised underperformance identified in the Dalli Plan as well as concerns about market surveillance in all sectors

- Increase efficiency across the devices regulatory network by enhancing and sharing of workload and more effective co-ordination and communication of pan-European safety issues.

Included in the objectives of the CAMD is the development of a website to enable stakeholders to easily locate and navigate between the CAMD and the major projects it has initiated.

2. Requirements

a) Purpose

To provide a website that:

- Incorporates the information and communication requirements of the CAMD and current and future Joint Action projects to stakeholders
- Has strong linkage to the EU Commission website to enhance stakeholder's ability to navigate the regulatory landscape and locate appropriate organisations and information
- Is an asset to stakeholders in all participating member states, enhancing engagement and transparency.

b) Audiences

The audiences for the website are varied:

- CAMD partners (key people who are working on the Joint Action project via one or more of its major groups)
- Devices regulatory staff working in Competent Authorities (CA) across all EU member states and the European Economic Area (EEA)
- Industry - trade groups and professional bodies across EU member states and the EEA
- Industry - manufacturers of medical devices across EU member states and the EEA
- Healthcare professionals across all EU member states and the EEA
- Patients across all EU member states and the EEA
- Media across all EU member states and the EEA

c) Content

Content will be developed and provided to the supplier by the CAMD project team at appropriate points in the project development. *See Ideal / indicative project timetable.*

d) Language

The website will be in English but we would want to consider including a free ware translate function or design so that can be effectively translated by Google etc

e) Content management system (CMS)

The supplier will build the site in open source, using an easy-to-use CMS. We are assuming there would be no licence fee if written in open source. Once the website

is built the CAMD project team will take over content management. A number of project managers will need access from various member states to upload and update information.

The supplier will provide reasonable training and ongoing support in the use of the CMS for the duration of the project (to 31 December 2019).

f) Responsive design
The website should be optimised for use across a range of devices, browsers and operating systems.

g) Ongoing website maintenance
The supplier will maintain the site and make reasonable updates during the project lifespan (to autumn 2019) through an agreed number of ad hoc development days included in the contract. Significant additional changes within the lifespan will be subject to separate negotiation and agreement.

h) Website and content ownership
All content, the website and IPR is owned by CAMD's sponsoring agencies and the European Commission.

i) Timing
The website should be in place and in use before the end of April 2016 (Beta version) with a finished site ready no later than July 2016.

j) Accessibility
The website and its content needs to meet industry standards for accessibility for example Level AA of the Web Content Accessibility Guidelines (WCAG) 2.0.

k) Design style guidelines
We currently have a logo and are commissioning a basic style guide that will be available to suppliers.

l) Hosting
We require the supplier to host the website on a secure server that meets recognised industry standards for the duration of the project (to 31 December 2019).

m) Social media
We have registered @camd_europe with Twitter and are considering setting up a LinkedIn group, although at present our preference is to join existing medical devices discussion groups. We will consider other social media platforms once the project develops. We would like links from the website to social media including blogs.

n) Domain name
The following URL has been registered for use www.camd-europe.eu We have also registered www.camd-europe.org and www.camd-europe.net to avoid any potential confusion in the future. www.camd.eu has been registered by someone else but is not currently a live site.

A generic email will be set up to direct all initial project enquiries to: enquiries@camd-europe.eu

o) User testing

We expect the supplier to develop the website to agreed industry practices and standards: Discovery, Alpha, Beta, Live so the site meets user needs and is clear and easy to navigate. We envisage user testing by the supplier would be relatively light touch, probably involving a series of telephone conversations with relevant European stakeholders, followed by some practical virtual testing. Stakeholder contact details will be provided.

p) Website structure

While the final website structure should be based on user testing, we require a single CAMD website that will host the three distinct (but related) project areas below:

CAMD home page (public facing information and first point contact)

⇩

Project information accessed through separate password protection to each area

⇩

CAMD executive	**Quality of instructions for use of re-sterilisable surgical instruments** Joint Action (led by Austria)	**Market surveillance of medical devices** Joint Action (led by UK)	*Scalable up to include other future Joint Action projects as required*	*Scalable up to include other future Joint Action projects as required*
Discussion / info sharing forum	Discussion / info sharing forum	Discussion / info sharing forum	Discussion / info sharing forum	Discussion / info sharing forum

We anticipate further Joint Action projects will be agreed in the future so the site will need to be scalable to accommodate these. Suppliers should indicate prices for this.

We acknowledge this is not a complicated site and we anticipate the structure/navigation will not look hugely different from other joint action websites (see annex 1 for examples).

Our basic requirements for the structure are:

- A publicly accessible area that provides general high-level information, written in plain English, about the project and its progress, aimed at a uninformed audience

- Password protection for each of the separate areas (eg the CAMD executive and Joint Action areas). This will hold more detailed information required by specialist staff from member state's Competent Authorities to deliver the project's overall objectives.

- A discussion forum within each password protected area for partners to share ideas and information

- Ability to build subscriber list of interested stakeholders so we can provide email updates from the project / groups and other relevant issues

- ShareFile. We are considering a share file set up to share project information that we need to provide a link to from the site.

3. Project management

The supplier will be responsible for project management, initiating and running appropriate client meetings, stakeholder user testing and delivery of the website to specification, within agreed budget and time.

There will be a single UK point of contact from the CAMD team for the supplier to liaise with on project management but there will also be a requirement to liaise with appropriate other member states as required.

4. Ideal / indicative project timetable

Below is our suggested timetable which we expect will be subject to further negotiation with the chosen supplier.

Phase	Action	Date
1. Development	Kick off meeting	29/2/16
	Supplier provided with high-level content / stakeholders	29/2/16
	Discovery / user testing	Complete by 11/3/16
	Wire frames, report back to client	18/3/16
	Alpha development and testing	25/3/16
	Report back to client	1/4/16
	Launch beta testing	8/4/16
	Report back to client / final changes	15/4/16
	Development stage closes	22/4/16
2. Maintenance	Ongoing maintenance and handover	To 31/3/20

Tender responses

Suppliers should ensure the following additional information is included in their response:

1. Details of their approach to developing the website.

2. General supplier capabilities: background, qualifications, geographic presence, service offerings, organisational structure etc.

3. Technical expertise for website development, ongoing technical support and tactical delivery.

4. Examples of similar projects for other organisations.

5. A proposed action plan and timetable for development and delivery of the project using the ideal / indicative timetable supplied as a guideline.

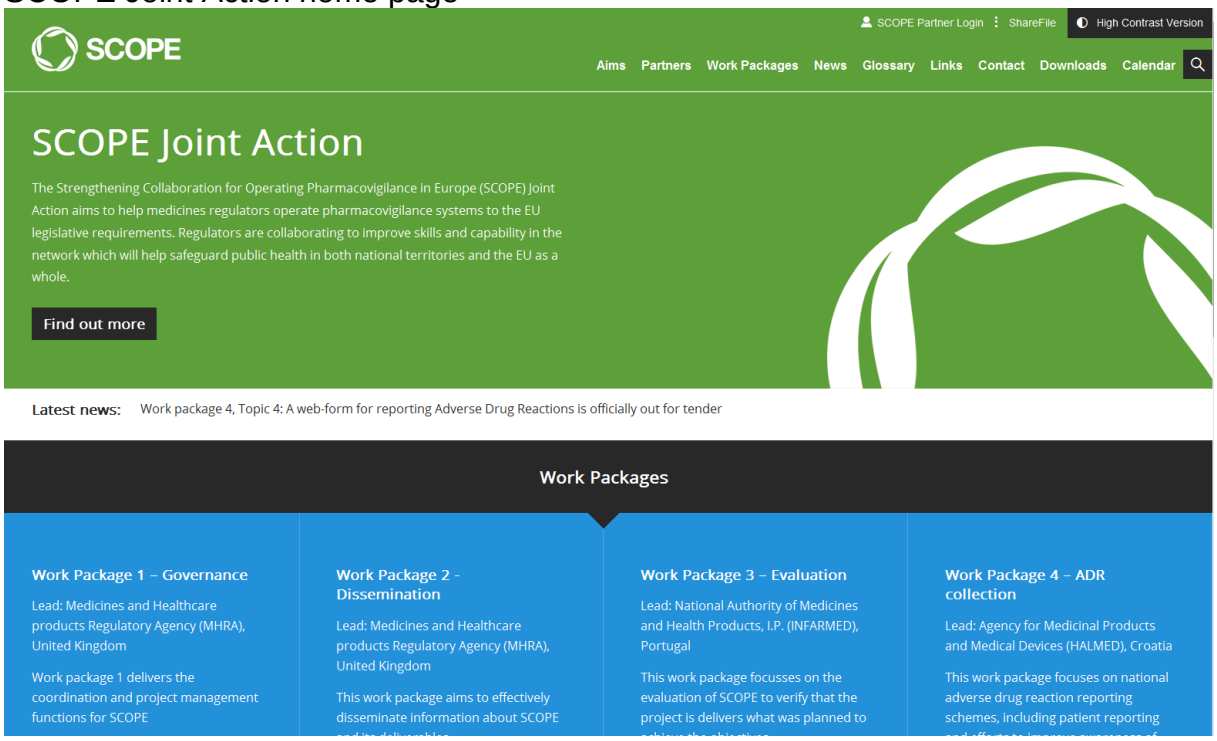
6. Outline how this project will be managed, who will be the central contact, the proposed project team and structure. Please include CVs and details of why they are suitable for delivery of this project.

7. A clear breakdown of budget allocation, including cost of adding pages / modules for additional Joint Action

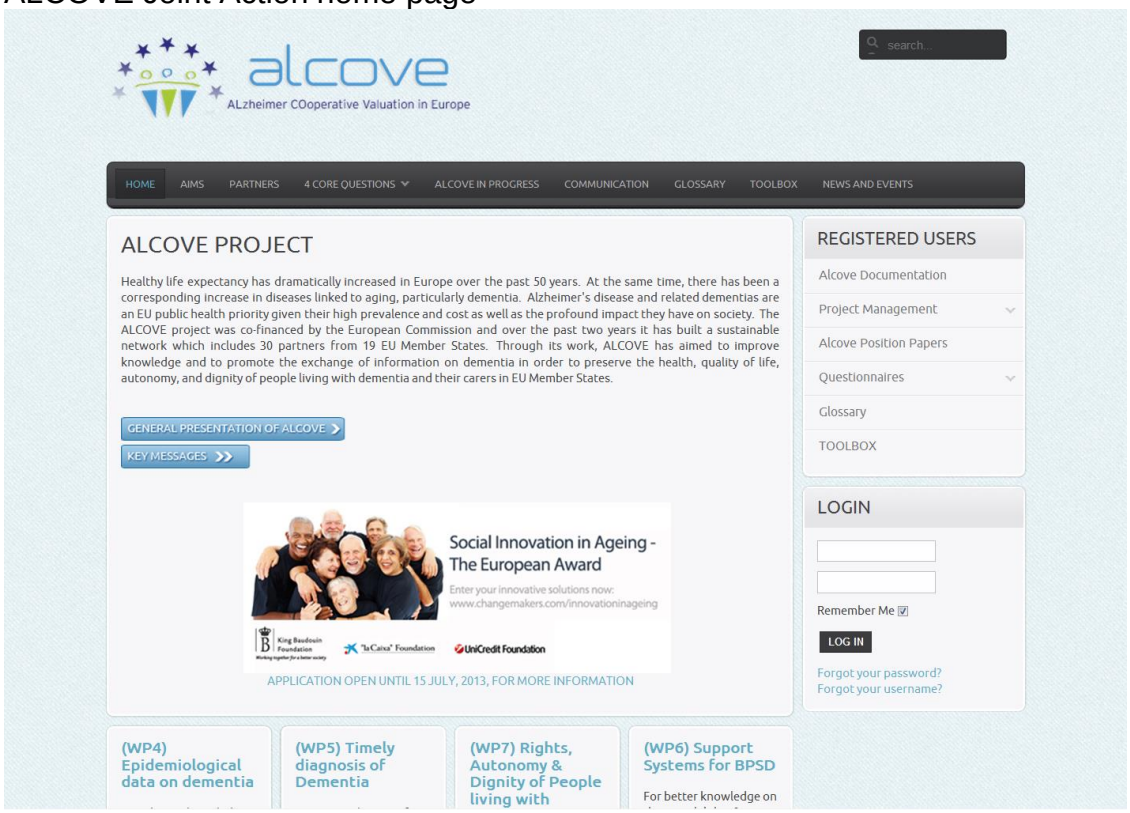
8. Suppliers should also make suggestions, not included in the specification, with costs for enhancing the functionality of the site.

Annex 1 – Screenshots of other Joint Action websites

SCOPE Joint Action home page



ALCOVE Joint Action home page



EPAAC Joint Action homepage