

Procurement of Cranio-Maxillofacial (CMF) Surgical Implants, Simulation & Training Equipment, Software and Related Services

Project on strengthening cranio-maxillofacial reconstructive surgery in Ukraine (Belgium-funded)

Terms of Reference

July 1, 2026

BACKGROUND AND CONTEXT

This procurement supports a project that aims to significantly improve the quality, accessibility and sustainability of cranio-maxillofacial (CMF) reconstructive surgery in Ukraine under the grant project UKR24001-10069 between Enabel and Superhumans.

CMF services are a high priority for the Government of Ukraine and the Ministry of Health under the National Health Strategy 2030 and the related Action Plan for 2025–2027, responding to the increased and growing need for CMF care caused by the ongoing war and casualties from repeated shelling of Ukrainian territory.

The project objectives are aligned with the priority areas of Ukraine–Belgium cooperation in health care set out in the Technical Agreement between the Ministry of Health of Ukraine and the Federal Public Service Health, Food Chain Safety and Environment of the Kingdom of Belgium, signed on 9 April 2025.

The goal is pursued by strengthening national capacity: developing and piloting a new model of CMF reconstructive treatment with post-operative follow-up, a referral system and case management; developing standards and clinical protocols ensuring continuity of care and infection control; building training programmes for interns and practitioners; integrating advanced technologies; and establishing sustainable support systems that ensure equitable access to care.

Specifically, the project establishes the foundation of a sustainable, high-quality and equitable CMF reconstructive surgery system, with:

- two clinical Centres of Expertise – in the west (Lviv) and centre (Kyiv) of Ukraine – recognised by the Ministry of Health; and
- two equipped training hubs at the national medical universities in Kyiv and Lviv.

PURPOSE AND OBJECTIVE OF PROCUREMENT

In line with the general objective, the project pursues three specific objectives (SO):

- SO1: Evaluate the current CMF care delivery system and practice in Ukraine.
- SO2: Develop and roll out a national comprehensive CMF reconstructive surgery and rehabilitation model, with corresponding training capacities.
- SO3: Expand CMF reconstructive surgery and rehabilitation services through improved quality of patient management, surgical care, infection prevention and control, referral and case management in the two Centres of Expertise in Lviv and Kyiv.

The procurement of goods and services covered by this Terms of Reference is an integral condition for achieving SO2 and SO3. The purpose of this procurement is to equip the two Centres of Expertise and the two university training hubs with the implants, simulation and training equipment, software and related engineering and training services required to deliver and teach complex CMF reconstructive surgery to international standards.

SCOPE OF MEDICAL GOODS AND SERVICES SUPPLY

All medical goods and services described in this Terms of Reference are to be procured under a single framework agreement with one supplier. This approach reflects the integrated nature of the required items: patient-specific implants, standard fixation materials, planning software, CMF simulation package per university and the associated case-management platform together form a single clinical workflow and must be fully interoperable.

The procurement decision is supported by the market analysis of manufacturers of the required goods and services (as detailed below) and is governed by the Procurement Policy of CO “CF “Superhumans”, both of which are attached as supporting documents to this Terms of Reference.

The following documents are attached and form part of this procurement package:

- Market Analysis of CMF Implant, Software and Equipment Manufacturers – documents the assessment of available suppliers and underpins the selection of a single-source supplier.
- Procurement Policy of CO “CF “Superhumans” – governs procurement procedures and the selection of suppliers for the organisation.

Delivery sites are the two Centres of Expertise and the two national medical universities located in Kyiv and Lviv.

Item	Description	Qty
Personalised PSI	Patient-specific implant designed from CT-based 3D planning for an individual CMF case	100
Standard implant	Non-patient-specific CMF implant or fixation component for standard trauma or reconstructive procedures	200
University site license package	Academic license package for university-based training, research and clinical 3D planning workflows	6
Image segmentation & 3D anatomical modelling license (floating)	License for CT/MRI segmentation and creation of 3D anatomical models	6
PSI & surgical guide design license (floating)	License for designing patient-specific guides, implants and 3D-printable medical models	6
CMF virtual surgical planning license (floating)	License for CMF virtual surgical planning (trauma, orthognathic and reconstructive workflows)	6

On-site training (8-hour day)	One-day on-site training at supplier's office on software use and CMF planning workflows	2
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Year by year forecast

Item	# of units 2026	# of units 2027	# of units 2028
Personalised PSI	30	50	20
Standard implant	60	95	45
University Site License package	2	2	2
Mimics Base (floating)	2	2	2
Mimics Design (floating)	2	2	2
Enlight CMF Full (floating)	2	2	2
Training in Materialise office (8-hour day)	2	0	0
Training online (hour)	16	0	0
Simulators for University	2		

GENERAL REQUIREMENTS FOR THE SUPPLIER

- Certification: all medical devices, implants, instruments and tools shall carry CE marking and be manufactured under an ISO 13485 quality management system. Implants shall be of medical-grade titanium with documented biocompatibility.
- Regulatory: all medical devices, implants, instruments and tools shall comply with applicable Ukrainian regulatory and legal requirements for import and use on the territory of Ukraine; the supplier shall provide, among others, all certificates and instructions for use and all conformity documentation required under Ukrainian law.
- Interoperability: standard and patient-specific implants, instruments and software shall together support a complete digital workflow (CT/DICOM → planning → design → manufacture → surgery → review). Equivalent solutions meeting the functional requirements are accepted.

- Language: software user interface and documentation in English (Ukrainian desirable); training delivered in English or Ukrainian.
- Warranty & support: equipment warranty and after-sales / technical support, with remote support capability suited to wartime logistics.
- Integrated capability: the supplier shall be capable of providing the full range of goods and services specified in these Terms of Reference, including software, planning services, patient-specific implant design and manufacturing, surgical instruments, training, and technical support.
- Local presence: the supplier shall maintain an office or an authorized representative in Ukraine to ensure timely coordination, communication, logistics support, regulatory compliance and resolution of operational issues throughout the project implementation period.

LOT 1 – SIMULATION & TRAINING EQUIPMENT FOR TWO UNIVERSITY TRAINING HUBS

Purpose: establish and equip two CMF training hubs at the clinical units of the two national medical universities (Kyiv and Lviv) for practising osteosynthesis and reconstruction of facial bones. Each hub shall comprise 10 full training workstations and 2 mentor stations, and shall be able to train up to 100 medical students and interns per university per year (up to 200 students/interns over the project period). The set-up shall enable recording and review of training procedures.

Training workstation configuration (per university)

- 10 full training workstations and 2 mentor stations, each providing a stable working surface, model fixation and the powered instruments below.
- 2 head-mounted video cameras for recording and reviewing surgical training procedures.

Medical equipment and training supplies (per university)

Scope boundary – medical items only.

The full simulation training hub set-up comprises both medical-specific equipment and training sets (covered by this framework agreement), medical items for microsurgery simulations and non-medical items such as furniture and general workstation infrastructure. Non-medical items and medical items for microsurgery training are procured under a separate procedure and are not part of this agreement.

CMF surgical instruments

CMF osteosynthesis instrument set per hub (forceps, screwdrivers, pliers, drill guides, drill bits, trays and organisers). The reference composition and indicative unit prices are listed in Annex A. Quantities follow the number of workstations/mentor stations per hub.

Training osteosynthesis plate & screw kits

Training sets of osteosynthesis plates and screws for upperface/trauma and reconstruction practice, with the compositions listed in Annex A (plate shapes, thicknesses, hole counts and matching screw kits).

Anatomical simulation models

Simulation models of the facial skeleton for practising osteosynthesis of the midface, mandible, zygomatic complex, orbital region and TMJ, with model holders. Indicative quantity of 100 units of each model type per university.

Patient-specific (PSI) training sets

Training sets reproducing patient-specific reconstruction and TMJ cases (titanium implants with polyamide guides) and the corresponding screw sets, as listed in Annex A, for practising personalised workflows.

LOT 2 – CLINICAL IMPLANTS AND PER-CASE MEDICAL ENGINEERING SERVICES

Purpose: enable the two Centres of Expertise to perform highly complex facial reconstructive surgery using patient-specific titanium implants and standard implant sets. The piloted model expects up to 300 patients, including up to 100 patients with a patient-specific implant need.

Patient-specific CMF implants (PSI)

- Custom titanium implants designed from the patient's CT-based 3D virtual planning, for reconstruction of the mandible, midface, orbital region and cranium, restoring anatomy, symmetry and function.
- Each case includes implant design and, where applicable, patient-specific surgical guides (planned osteotomies, resection, drilling and screw-entry points) and an anatomical model. ● Additive-manufactured medical-grade titanium; CE / ISO 13485.
- Indicative quantity: implants for 100 cases (one patient may require more than one implant).

Standard CMF implants and fixation

- Ready-to-use titanium plates and screws for trauma and reconstruction (midface, mandible, orbital, neuro/cranial), low-profile, with a full screw range and intermaxillary fixation components.
- Desirable: ability to combine standard plates with patient-specific guides and a digitally planned bending/outcome model, so that standard plates can be pre-bent to the planned anatomy before or during surgery.
- CE / ISO 13485 certified plates, screws and tools.
- Indicative quantity: implants for 200 cases (one patient may require more than one implant).

Per-case medical engineering services

- Image validation, virtual surgical planning, implant and guide design, and intraoperative remote support with 3D visualisation, delivered per clinical case.
- Indicative quantity: 300 cases.

LOT 3 – SOFTWARE LICENSES AND CASE-MANAGEMENT PLATFORM

Purpose: equip the two Centres of Expertise and the two universities with the software required for the complete CMF digital workflow, and train the responsible staff (at least one trained user per Centre of Expertise). License model: floating licences covering the two Centres of Expertise, with a term aligned to the project (approximately three years).

Functional software modules

- Module A – Image segmentation & 3D anatomical modelling: convert DICOM / CT / MRI / CBCT data into accurate 3D anatomical models; cleared for medical use.
- Module B – PSI & guide design (medical CAD): design patient-specific surgical guides, implants and 3D-printable medical models.
- Module C – CMF virtual surgical planning: trauma, orthognathic and reconstructive workflows, including osteotomy and reposition planning and cutting/positioning-guide preparation.
- University academic site-license package: multi-seat academic licences for university-based training, research and clinical 3D-planning workflows.

Online case-management platform

- Secure upload of CT / MRI / CBCT scans; case creation, tracking and notifications; interactive 3D viewer; mobile access; case communication with the engineering/design team; transparent tracking of material use and tool inventory.
- Desirable: extended-reality (AR/VR) case review compatible with common head-mounted devices.

Software training

- On-site training (8-hour days) and online training/technical-support hours for the responsible staff of the two Centres of Expertise.

STANDARDS, CERTIFICATION AND QUALITY

- CE marking and ISO 13485 quality management system for all medical devices, implants, instruments and tools.
- Medical-grade titanium with documented biocompatibility; controlled additive-manufacturing quality for PSI; sterilisation compatibility and product traceability.
- Software: medical-device clearance where the module qualifies; secure handling of patient DICOM data with privacy safeguards aligned to applicable data-protection rules.
- All certificates, declarations of conformity and instructions for use provided in English.

DELIVERY, INSTALLATION AND ACCEPTANCE

- Delivery to the Centres of Expertise and universities in Kyiv and Lviv, with customs handling for import into Ukraine.
- Equipment (Lot 1) and software (Lot 3): installation/commissioning and basic user training included.
- Patient-specific implants and per-case engineering (Lot 2): delivered case by case – the Centre submits the patient CT and clinical data via the platform; the supplier returns the design for approval; the implant is then manufactured and delivered by courier. Standard implants and instrument sets are delivered as complete sets.
- Acceptance against the specification, the supplied certificates and a functional check at the delivery site.

COMMERCIAL AND CONTRACTUAL CONDITIONS

- A framework agreement shall be concluded with the selected supplier(s) for the full duration of the project; the full commercial conditions are fixed in that framework agreement.
- Patient-specific implants and per-case engineering cannot be planned in advance of an identified patient, a CT scan and an approved surgical plan. Orders are therefore placed case by case under the framework agreement, and payment is made against invoices issued for each actual order.
- Payments are made from the project grant account to the supplier's account (the supplier may be an EU / Belgian entity); the contract currency is the euro (EUR).
- Responsibilities: the supplier is responsible for the timely delivery of all goods and services ordered; Superhumans is responsible for providing all data required to design and manufacture the implants (CT data, clinical information and approvals).
- The framework agreement remains valid until the end of the project, in order to simplify the documentation flow and accelerate actual delivery following each individualised order.

ESTIMATED BUDGET AND REFERENCE VALUES

Reference values below are derived from current market quotation data and are indicative for budgeting only; they are not binding prices and do not designate any manufacturer. The procurement must remain within the approved project budget envelope. Approved budget envelope: total €2,487,636.

Budget line	Qty
Output 2	
Equipment for simulation class for practicing osteosynthesis and reconstruction of facial bones (for 2 medical universities)	2

Output 3	
Medical engineering per case	300
Patient-specific implants	100
Medical materials for surgery with standard implants (medical supply, analysis per case)*	200
Software	6
Platform (case-management)	3

*Among other goods the line includes the standard plates (implants) for 200 patients in average receiving 2,7 surgeries per case

SUPPLIER ELIGIBILITY AND QUALIFICATIONS

- Manufacturer or authorised representative / distributor of the offered goods.
- Valid CE certificates and ISO 13485 quality management system.
- Demonstrated track record in CMF implants / software (references).
- Ability to deliver to Ukraine under current logistics, including customs handling.
- Clinical / medical-engineering support capacity (remote; local presence in Ukraine or the EU is an advantage).
- Software available in English and capacity to deliver staff training.

TIMELINE AND DELIVERABLES

Deliverable	Timing (indicative)
Framework agreement signed with selected supplier(s)	On award
Lot 1 – training hubs equipped and commissioned (Kyiv, Lviv)	Within agreed delivery period after signing (no later than October 31, 2026)
Lot 3 – software deployed and responsible staff trained	Within agreed delivery period after signing (no later than September 30, 2026)
Lot 2 – standard implant sets delivered; PSI and per-case engineering available on a rolling case-by-case basis	Throughout the project period within agreed delivery period per case
Final acceptance and close-out	On completion of the grant project (September 30, 2028)

ANNEX A – LOT 1 REFERENCE ITEM LIST

Indicative reference composition derived from market quotation data; brand names have been removed and equivalent items meeting the functional description are accepted. Quantities per hub follow the workstation/mentor-station count and the model quantities described above.

CMF Surgical Instruments

Instrument
Screw holding forceps
Plate holding forceps
Plate applying instrument
Plate bending 3-point pliers
Screwdriver handle (system connection)
Screwdriver blade, dental connection (cruciform)
Screwdriver blade, system connection (cruciform)
Screwdriver handle, dental connection
Screwdriver blade, easy-grip
Flat forceps
Wire and plate cutting pliers
Plate holding forceps (heavy)
Plate bending forceps
Plate cutting pliers
Plate bending lever
Depth gauge for drill-holes
Reconstruction plate bending 3-point pliers
Drill guide – short
Drill guide – long
Drill bit Ø1.20 × 8.0 × 50 mm (for 1.5 mm screws)

Drill bit Ø1.45 × 18.0 × 70 mm (for 2.0 mm screws)
Drill bit Ø1.80 × 25.0 × 80 mm (for 2.4 mm screws)
Trauma & reconstruction tray (polyamide)
Trauma / upperface tray (polyamide)
Universal screw-kit organiser (polyamide)
Instruments organiser
Screwdriver blade, miniscrews (system connection)
Screwdriver handle (system connection, heavy)

Training plate & screw kits

Kit
Training set of plates – Trauma/Upperface (assorted refs, 0.6 mm; straight, L, orbital curved, square)

Training set of plates – Recon & Trauma (1.0 mm condylar; 1.5 mm straight/curved; 2.5 mm curved, hemi-/total mandibular reconstruction)
Universal screw-kit organiser – Trauma/Upperface (34 screws/kit, 1.5 & 1.8 mm)
Universal screw-kit organiser – Recon (86 screws/kit, 2.0–2.3 mm & 2.4/2.7 mm locking, 2.0 mm IMF)

Anatomical simulation models

Model
Facial-skeleton simulation model – midface osteosynthesis
Facial-skeleton simulation model – mandible osteosynthesis
Facial-skeleton simulation model – TMJ osteosynthesis
Model holder

Patient-specific (PSI) training sets

Training set
Training set – Personalised Recon (Ti implants + polyamide guides)
Training set – Personalised TMJ (patient-specific implants)
Training set – screw set for Personalised TMJ & Recon (2.0 mm)