General Questions

1) What is the relationship between the AAOS Registry Program and each of its anatomical registries?
The Shoulder & Elbow Registry (SER) is part of a family of registries, The AAOS Registry Program, that share the same technical infrastructure, harmonized data element lists, and an ability for participants to track patients longitudinally. Each Registry has its own Steering Committee composed of clinical experts and stakeholders who provide leadership for Registry development. All AAOS Registries are built on the RegistryInsights® platform.

2) What is SER?
SER consists of three modules: shoulder arthroplasty, elbow arthroplasty, and rotator cuff repair and collects procedural data on patients across the United States. Sites and surgeons can use this data to help improve patient care by informing the development of performance metrics and standards of care, and supporting quality improvement initiatives and advocacy across orthopaedics.

3) What is the value of participating in SER?
An evidence-based registry like SER is a cost-effective way to benchmark risk-adjusted data and gain insights that you and your team can use to drive improved patient outcomes. These improvements can also help meet the requirements of insurance providers and the Centers for Medicare & Medicaid Services (CMS) when documenting performance for value based care.

4) Is there an additional fee for sending the Registry Procedural, Post-Operative, and/or Patient-reported Outcome Measures (PROMs) File Layout data?
No, all three layouts are included with participation and participants in SER can submit data for each of the modules. See more about types of data submitted in the Data & IT section below.

5) What is the cost to participate in SER?
A one-year subscription to SER is $3,500, plus a one-time $750 configuration fee. For more information, please contact RegistryEngagement@aaos.org.
6) **What is included in a SER subscription?**

- All-access Authorized User (AU) to manage site participation, *one account included, with additional AUs available*
- Data Submission User accounts to manage submissions, *unlimited accounts included*
- Dashboard Surgeon User accounts to access dashboards on their patient care, *unlimited accounts for AAOS member surgeons*
- Ability to re-use data for performance and quality improvement initiatives, for example submissions to the Merit-based Incentive Payment System (MIPS), the American Board of Orthopaedic Surgery Maintenance of Certification program, and other distinction programs
- Dashboard access to national comparison and benchmarking reports
- Access to our patient-reported outcome (PRO) platform to administer and analyze your patient surveys
- Comprehensive onboarding and training
- Access to monthly Registry webinars and ongoing data and technical support
- Facility's recognition in *Annual Report* and AAOS website

7) **How much time does it take to administer the SER program? Will I need to hire any additional employees?**

Assigned full-time employees (FTEs) are not required for participation, but workload will vary depending on the number of procedures per site. AAOS Registry staff will work closely with you to help decrease the data burden by building queries, or having your technology vendors do so as part of our *Authorized Vendor Program*. Data specifications and a data dictionary are provided for each Registry module to give guidance on what data to collect and what format to submit in.

8) **How long does it take to onboard my site and start participating in the Registry?**

It varies by site, but is typically completed in 60 days. You will be assigned a Registry Support Specialist who will work with you to ensure a successful onboarding.

9) **How can I promote participation in the AAOS Registry Program to my organization’s stakeholders?**

Marketing and communications support is available to help promote your site’s involvement with the Registry. This includes internal communications with your surgeons and externally with your patients. Additionally, through the User Group Network (Unet) you can connect with other Registry participants to learn what has worked well at their sites. We also provide a slide deck of tables and figures that are published in our *Annual Report* that can be shared with your surgeons.

10) **I may be interested in joining SER. Who do I contact?**

Please contact us at *RegistryEngagement@aaos.org* to learn more.
**Data & IT**

1) **How should my data be uploaded to the Registry?**

Data can be sent via an SFTP, the HTTPS site or by using the drag-and-drop feature via the RegistryInsights platform. Our secure transfer process implements both an SFTP and a HTTPS service for a site to submit data directly to us. Both services present SER extended validation certificates and automatically encrypt all data upon landing.

If you do not have an SFTP client on your desktop, we suggest using the HTTPS. You may use any web browser to do so. If you already participate in AJRR, the data submission process is similar.

2) **What types of data are submitted to SER?**

SER will collect three types of data:

- **Procedural** includes data related to the patient, site, surgeon, and procedure. The layout also consists of elements like comorbidities and length of stay.

- **Post-operative** includes 90-day readmission information and enables risk-adjusted outcome comparisons.

- **Patient-reported Outcome Measures (PROMs)** includes data from surveys submitted by the patient.

3) **How often should data be submitted?**

Because feedback reports are more useful when data is submitted more frequently, the AAOS Registry Program recommends monthly submission. Participants are considered active if they submit every 90 days; however, we will accommodate each participant’s submission as needed.

4) **Why should I consider a PRO Program?**

A patient-reported outcome (PRO) is defined as any information on the outcome of health care obtained directly from patients without modification by clinicians or other health care professionals. It helps provide a 360-degree view of a patient’s healing. One of the ways RegistryInsights supports SER is by presenting patient-reported outcome measures (PROMs) collected through a survey process. The survey captures the patient’s self-assessment of their health across a variety of parameters. It is an important tool used in PRO programs. Read “Starting a Goal-Driven Patient-Reported Outcomes Program” for more information.

5) **What follow-up timeframe for PROMs do you recommend?**

PROMs guidelines from groups such as the International Consortium for Health Outcome Measurement (ICHOM) have recommended pre-operative (baseline) and one-year follow-up as appropriate time points for data collection to provide meaningful data for comparing outcomes across providers.
Each time point will have a two-month window for data collection. SER’s platform will allow for other time points (e.g., three-month, six-month, etc.) to be submitted and stored in SER’s database should you wish. However, national benchmarks will only be reported for pre-operative and one-year outcome.

6) **Can you accept retrospective data?**
   Yes, we accept retrospective data for in all three layouts from 1/1/2016 moving forward.

7) **How do you make sure patient information is linked for longitudinal patient follow-up and outcomes?**
   We collect unique patient identifiers, like Social Security numbers, to ensure individual patients are properly identified. This allows us to track and link multiple procedures to the same patient. Revisions and additional procedures may not be done by the same surgeon or at the same site, so a unique patient identifier is critical.

8) **What type of training do you provide for the RegistryInsights platform?**
   SER participants receive one-on-one training to get started and a User Guide that provides a step-by-step reference for accessing and utilizing the RegistryInsights system. General platform training and PRO platform training webinars are also held regularly, and webinar recordings are available for download. If additional training or demonstrations are needed, we are happy to assist you.

9) **How do you keep the data in the Registry secure?**
   As an organization that improves the quality of care through data processing, AAOS understands the significance of the confidentiality, integrity and availability of our data infrastructure. AAOS implements administrative, physical and technical safeguards and applies them to Protected Health Information (PHI) in any form from destructive forces and from unwanted actions of authorized and unauthorized users – both intentionally and unintentionally. AAOS, as a Health Insurance Portability and Accountability Act (HIPAA) Business Associate, recognizes and acknowledges the inherited responsibility of securely safeguarding PHI data and ensuring data privacy through proper enforcement of HIPAA due diligence actions. These actions follow all the 1996 HIPAA privacy rules and PHI regulatory requirements. PHI is secured, maintained, and released in accordance with all applicable federal and state laws, rules and regulations, including all the HIPAA regulatory requirements. The AAOS Information Security, Compliance, and Privacy Officers ensure that all staff obtain a certificate of HIPAA training completion. All AAOS personnel who process, generate reports, or otherwise have contact with PHI must uphold the patient’s right to confidentiality. This policy refers to all information resources, whether written, verbal, or electronic, and whether individually controlled, shared, stand alone, or networked.
Legal

1) Which agreements are required to join SER?
   Two agreements need to be signed – Business Associate Agreement/Data Use Agreement (BAA/DUA) and Participation Agreement. The Participation Agreement is required and outlines most of the terms and conditions of the SER/site relationship, for example: how and when data should be submitted, term and termination, fees, ownership and confidentiality of data, and other terms and conditions for participation. The BAA/DUA Agreement is required to comply with our joint responsibilities as covered entity (the site) and SER, as your business associate and recipient of a limited data set, as required by the Health Insurance Portability and Accountability Act of 1996.

2) Will each site’s Institutional Review Board (IRB) need to review participation?
   Each site should check with their local IRB representative, but SER has obtained a centralized IRB approval for waiver of consent. Please contact us at RegistryAnalytics@aaos.org, if you have further questions or need assistance with documentation for your site.

To learn more, please contact a Registry Engagement Associate
   (847) 292-0530 | RegistryEngagement@aaos.org
   Or visit www.aaos.org/registries/ser