

# International Cellular Medicine Society Open Treatment Registry





Welcome demo

[Logout](#)



### Main Menu

- [Home](#)
- [Patients](#)
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- [Users](#)

### Follow Up Orthopedic Form - Patient ID : 031110CLINICA0310

Pain Intensity :

Sleeping :

Personal Care :

Travel :

Recreation :

Sitting :

Headaches :

Work :

Frequency of Pain :

Lifting :

Walking :

Standing :

Reading :

Concentration :

Have you received any re-implants since the last follow up?

Have you developed any symptoms or signs or diagnosed new diseases since last contact?

Overall how do you feel now compared to prior to the procedure?

What % change overall?   
(put negative # if worse)

Range of Motion :

Strength :

Did you experience any complications you believe may be due to the procedure?

If yes or maybe, please explain

Have you been diagnosed with any new illness since the procedure?

If yes, please explain

## The ICMS Open Treatment Registry

The Open Treatment Registry is a cellular medicine outcomes and complications database that is tracked and updated by an independent third party.

The registry is managed the International Cellular Medicine Society as a 3<sup>rd</sup> party, nonprofit organization.

The Open Treatment Registry is supported by patients who provide the ICMS with a one time, per procedure donation of \$350. Patients are contacted by the ICMS on an established schedule and procedure specific observational questionnaires are administered.

# Why would a stem cell clinic want to participate?

To Protect Stem Cell Therapies as the practice of medicine

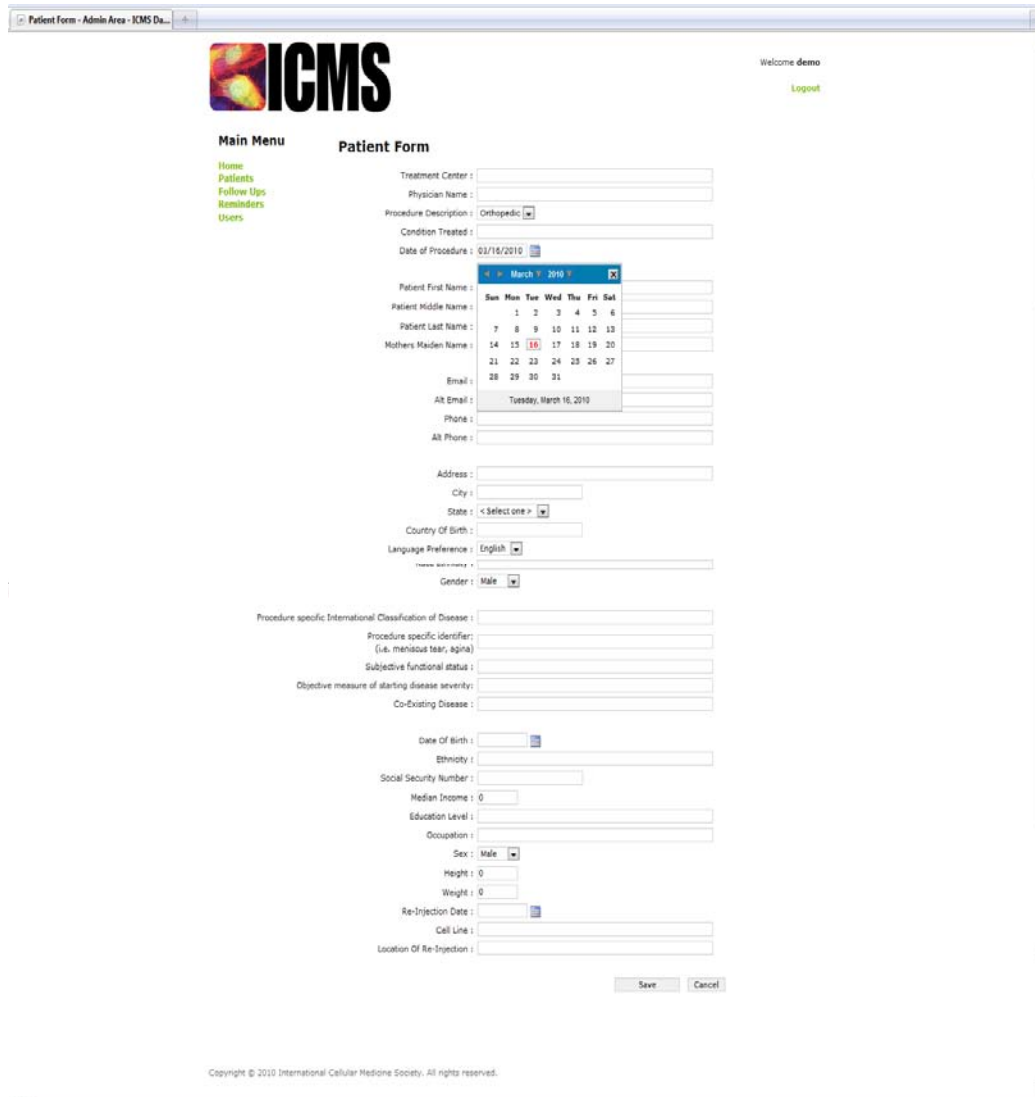
Because Stem Cell Therapy is Under Fire by Big Pharma

1. **Credibility :**  
Self reported complications and outcomes are less credible than those collected by an independent third party.
2. **Long term patient tracking:**  
The ICMS provides comprehensive outcomes and complications tracking at 3, 6 and 12 months, annually for the first 5 years, and then again at 10 years and at 20 year after the procedure.
3. **Independent review and evaluation of patient complications:**  
The ICMS reviews all patient data and will alert the clinic of any reported adverse events and complication



# The ICMS

## Open Treatment Registry FAQs



The screenshot shows the 'Patient Form' interface in the ICMS system. The browser title is 'Patient Form - Admin Area - ICMS Da...'. The page features the ICMS logo and a 'Welcome demo' message with a 'Logout' link. A 'Main Menu' on the left includes links for Home, Patients, Follow Ups, Reminders, and Users. The 'Patient Form' section contains various input fields and dropdown menus for patient information, including:

- Treatment Center
- Physician Name
- Procedure Description (dropdown: Orthopedic)
- Condition Treated
- Date of Procedure (calendar: 03/16/2010)
- Patient First Name (calendar: March 2010)
- Patient Middle Name
- Patient Last Name
- Mothers Maiden Name
- Email
- Alt Email (calendar: Tuesday, March 16, 2010)
- Phone
- All Phone
- Address
- City
- State (dropdown: <select one>)
- Country Of Birth
- Language Preference (dropdown: English)
- Gender (dropdown: Male)
- Procedure specific International Classification of Disease
- Procedure specific identifier (i.e. meniscus tear, arnia)
- Subjective functional status
- Objective measure of starting disease severity
- Co-Existing Disease
- Date of Birth (calendar)
- Ethnicity
- Social Security Number
- Median Income
- Education Level
- Occupation
- Sex (dropdown: Male)
- Height
- Weight
- Re-Injection Date (calendar)
- Cell Line
- Location Of Re-Injection

At the bottom of the form are 'Save' and 'Cancel' buttons. The footer contains the text: 'Copyright © 2010 International Cellular Medicine Society. All rights reserved.'

Q: What is tracked in the Treatment Registry?

A: The ICMS tracks objective and observational measure outcomes and complications as reported by patients. The ICMS also tracks cell line, procedure and clinic data.

Q: What is a cell line?

A: A cell line is the specific stem cell treatment used by a clinic in treatment. A cell line is defined by the collection, processing, implantation process, and disease treated by a stem cell clinic.

Q: How does the ICMS track cell lines?

A: The ICMS assigns a unique identifier for every cell line used by every clinic. When patients are entered into database, the cell line used in that procedure is recorded.

Q: Can a clinic have more than one cell line?

A: Yes. Clinic that utilize multiple cell lines for different treatments must register each cell line.

Q: Is cell line information kept private?

A: Yes. The ICMS does not require disclosure of proprietary information on how a clinic collects, processes and implants its cell line. The applications for cell line identifier requires that the clinic provide general information on cell source, processing and implantation methods. All clinic data provided in the Treatment Registry agreement is kept confidential.

# The ICMS

## Open Treatment Registry FAQs

Q: Is the user interface customizable?

A: Yes. Both the patient in-take and the follow up forms are customizable for each clinic in both text and language.

Q: Does the ICMS maintain the right to access, review and evaluate data stored within the Treatment Registry?

A: Yes.

Q: Who determines what follow up questions are asked?

A: The ICMS works with Clinics to establish standard observational and objective measures follow up questions for each procedures performed. A standard set of complication questions is asked of every patient.

Q: Are clinics able to advertise their participation in the Treatment Registry?

A: Yes. Advertising that an independent nonprofit is providing patient outcome tracking is a powerful marketing tool for clinics. Clinics are not allowed to imply that they are accredited by the ICMS because of their participation in the Treatment Registry.

Q: Do clinics need to enter all of their patients into the Treatment Registry?

A: Yes. All patients treated after the agreement has been signed must be entered into the Treatment Registry.

Q: Does data from previous patient data need to be entered into the Patient Registry?

A: The ICMS does not require that data from patient treated prior to an agreement be entered into the Treatment Registry. Clinics are welcome to provide historic data for inclusion into the Treatment Registry.

Q: Will the ICMS provide follow up for previous patients?

A: No. Patients treated prior an agreement will not be tracked by the ICMS.

Q: Who controls the data in the Treatment Registry?

A: Data stored within the Treatment Registry belongs to the clinic. Clinics empower the ICMS to contact patients and actively solicit follow up and track outcomes.

Q: Is patient medical information kept private?

A: Yes. The ICMS adheres to strict privacy guidelines in accordance with the Health Insurance Portability and Accessibility Act of 1996 (HIPAA). Patients are assigned a unique identifier and their confidential medical information is kept private and secure.

Q: Who sets access to the data?

A: Clinics control access to their own data within the Treatment Registry. Clinics may choose to share all, none or selected collections of data with the general public, members of the ICMS or researchers.

What does it cost to participate in the Treatment Registry?

Q: Who has publication rights for data stored within the Treatment Registry?

A: Publication rights are shared by the clinic and the ICMS. The clinic will maintain the right of review and will be authorship credit for any publication.

Q: What is the difference between the Treatment Registry and the Certified Registry?

A: The Treatment Registry is open to all stem cells clinics. The Certified Registry is only available to those stem cell clinics that have been fully accredited by the ICMS.



## The ICMS Open Treatment Registry FAQs, cont.

Q: Will patient outcomes will be reported back to the clinic?

A: Yes. Clinics can request customized patient, clinic or procedure reports from the ICMS.

Q: How does patient data get entered into the Treatment Registry?

A: Every clinic is provided a customized interface to the ICMS Treatment Registry. Clinic staff inputs all the patient data into this web page at the time of the procedure.

Q: How is the ICMS paid?

A: There are two options for payment: 1) Patients can pay the ICMS directly by credit card or 2) patients can pay the \$350 to the clinic. With the second option, the ICMS will invoice the clinic on a monthly basis for all the patients entered and the clinic can pay by either credit card or wire transfer.

Q: Will clinics be alerted to changes in the patient's health or well being?

A: Yes. The ICMS will alert the clinic about adverse events that arise from the patient's follow reporting.

Q: Is the clinic responsible for following up with patients after complaints are made?

A: Yes. All patient complaints will be flagged in the Registry for clinic adjudication. This flag will remain until the clinic provides the ICMS with proof that the complaint has been adjudicated.

Q: What happens if a clinic does not adjudicate complaints?

A: Failure to adjudicate patient complaints may result in a public announcement of expulsion from the Registry and a declaration from the ICMS of failure to comply with ICMS standards.

Q: Why should a clinic participate?

A: Transparency and accountability send a strong message that clinic 's value the long term wellness of patients.

Q: Who pays the ICMS?

A: Patients provide a one-time, \$350 donation to the ICMS per procedure to be entered into the ICMS Treatment Registry. As a 501(c)(3) nonprofit, donations to the ICMS may be tax deductible.

Q: Why is independent follow up important?

A: The ICMS works for patients, not the clinic. Data collected by the ICMS is based purely on patient reporting and is not influenced other factors.

Q: How often will the ICMS follow up with patients?

A: The ICMS will follow up with patient at 3,6 and 12 months, and then at 2, 3,4,5, 10 and 20 years after the procedure.

Q: How will the ICMS conduct the patient follow up?

A: The follow up is automated. Patients will receive an email with a link to a private web page to answer follow up and complications questions. If patients do not respond to the email, the ICMS will contact the patient by phone and then letter.

Q: Will patient outcomes will be reported back to the clinic?

A: Yes. Clinics can request customized patient, clinic or procedure reports from the ICMS.

Q: How does patient data get entered into the Treatment Registry?

A: Every clinic is provided a customized interface to the ICMS Treatment Registry. Clinic staff inputs all the required patient data into this secured web interface.