“Hands-on the Chilean Regulations”

Sao Paulo, 20 October 2013

Navigating the new health

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# 1. Regulatory Framework: Regulations

<table>
<thead>
<tr>
<th>Main Regulations</th>
<th>Published</th>
<th>Scope</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sanitary Code, Decree N°725/1967</td>
<td>31 Jan 1968</td>
<td><strong>Art. 102</strong> Only registered medications could be marketed/distributed in Chile, but the sanitary authority could authorize the provisional use of non registered medications for scientific research or clinical trial purposes</td>
</tr>
<tr>
<td>D.S. N°140 (Health Services’ Regulation)</td>
<td>21 Apr 2005 valid since 21 Oct 2006</td>
<td><strong>Art. 46</strong> Site’s Direction to authorize a clinical trial previous favorable opinion of the corresponding Ethical-Scientific Committee</td>
</tr>
<tr>
<td>D.S. N°3/2010</td>
<td>25 Jun 2011 valid since 26 Dec 2011</td>
<td><strong>Art. 21c</strong> authorization for the provisional use of pharmaceutical products for scientific research or clinical trial purposes previous favorable opinion of the corresponding ethics committee (s) <strong>Art. 23</strong> clarifies that same process is followed for a new indication (previous register does not apply)</td>
</tr>
<tr>
<td>Technical Norm N° 57</td>
<td>04 Jun 2001</td>
<td>Regulation on the performance of clinical trials using pharmaceutical products in human beings</td>
</tr>
<tr>
<td>Circular N°4</td>
<td>05 Sep 2009</td>
<td>Updated in the requirements and conditions for approving the use of an unauthorized medication for a clinical trial</td>
</tr>
</tbody>
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<td>Law 19628</td>
<td>28 Aug 1999</td>
<td>Protection of personal information</td>
</tr>
<tr>
<td>Law 20120</td>
<td>22 Sep 2006</td>
<td>About scientific research in human beings, their genome and human cloning prohibition</td>
</tr>
</tbody>
</table>
| D.S N°114 /10 (including Decree 30)   | 19 Nov 2011 valid since 14 Jan 2013 | Regulation to Law 20120  
Art.19: Comisión Nacional de Bioética  
Art. 22: Comisión Ministerial de Ética de la Investigación en Salud (CMEIS) |
| Resolution N°00441                   | 13 Feb 2012      | Establishes and updates the process to notify adverse events occurred during clinical trials carried out in Chile |
| Resolution N°1847/12                 | 23 Jul 2012      | Inspection Guide for Clinical Pharmacological Studies                 |
| Resolution N°1553/12                 | 09 Aug 2012      | Replace Res. N° 334 /11 (where ANAMED department was created) & subdepartments structure |
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<td>Resolution N°1448/13</td>
<td>17 Jun 2013</td>
<td>Modify Res. N°1552/12, which establish the internal structure of ANAMED</td>
</tr>
<tr>
<td>Law 20584</td>
<td>24 Apr 2012 valid since 01 Oct-2012</td>
<td>Regulates the rights and duties people have in relation to actions related to their health assistance. Associated regulations: Decree N° 31, 35 &amp; 40 (26 Nov 2012); Decree N° 41 (15 Dec 2012); Decree N° 38 (26 Dec 2012); Circular N°15 of 18 Apr 2013 (Informed consents for people participating in scientific research)</td>
</tr>
</tbody>
</table>

International Regulations


**GCP** (Good Clinical Practices) & **ICH** (International Conference on Harmonization Regulations)

“**Documento de las Américas, 2005**”

[Ref: http://www.ispch.cl]
The Public Health Institute of Chile in Spanish ISP = Instituto de Salud Pública de Chile, is the regulatory authority of Chile.

Within the ISP, is ANAMED = Agencia Nacional de Medicamentos (National Agency of Medications) who coordinates the following subdepartments and units:

- **Clinical Trial Unit**, department that reviews the clinical trials (authorizes or rejects the importation of not registered medications (or not for the specific indication under investigation) to be used in Clinical Trials; evaluates the documents submitted for this request and the related modifications; inspects the correct use of the Investigational Products at the research centers, pharmaceutical companies and CROs).

- **Subdepartment of Pharmacovigilance (ex CENIMEF)**, is the National Center of Information of Drugs and Pharmacovigilance of the ISP, that receives all the Safety Reports for registered Drugs.

- **UCIREN**, department that reviews and clears the Use and Disposition for each IP import, to be thereafter released by the Customs Service.

Ref: http://www.ispch.cl
1. Regulatory Framework: Regulatory Bodies

ISP

INSTITUTO DE SALUD PÚBLICA DE CHILE

ANAMED

Departamento Agencia Nacional de Medicamentos de Chile – ANAMED

Publicado en Instituto de Salud Pública de Chile (http://www.ispch.cl)
1. Regulatory Framework: Regulatory Bodies

**Regulatory Bodies**
- Drug Information Association
- www.diahome.org
- UCIREN
- ANAMED
- Subdepto. de Farmacovigilancia

**Diagram**
- DIRECCIÓN
- ISP
- DEPARTAMENTO AGENCIA NACIONAL DE MEDICAMENTOS
- Secretaría
- Unidad Ejecutiva
- Unidad de Control Documental
- Unidad de Gestión y Adm. de sist. Informáticos
- Unidad de certificación e Internaciones (UCIREN)
- Subdepto. Farmacovigilancia
- Resolution N°1553/12

**Subdepartments**
- Subdepto. Registro y Autorizaciones Sanitarias
- Subdepto. de Inspecciones
- Subdepto. Lab. Nacional de Control
- Subdepto. de Biofarmacia y Bioequivalencia
- Subdepto. de Dispositivos Médicos
- Subdepto. de Estupefacientes y Psicotrópicos

**Sections**
- Sección Registro Farmacéuticos
- Sección Productos Nuevos
- Sección Cosméticos
- Sección Estudios Clínicos
- BPM y BPL
- Sección Autorización Establecimientos
- Sección Denuncias
- Sección Farmacia
- Sección Análisis Físicos y químicos
- Unidad Pruebas Biológicas
- Unidad Microbiología
- Unidad de Desarrollo Analítico
- Sección Información de Medicamentos
- Sección Evaluación, Registro e Inspección
- Sección Tecnovigilancia

**Date**
- since 2011
1. Regulatory Framework: Regulatory Bodies

Subdepartamento de Registro: Organigrama

JEFATURA
Helen Rosenbuth

- Comité de Calidad
- Archivo
- Sección Registro Farmacéuticos
- Sección Productos Nuevos
- Sección Cosméticos
- Sección Estudios Clínicos
  - Oficina de Evaluación

SECCIÓN DE ESTUDIOS CLÍNICOS
Ethical-Scientific Evaluation Committee
commonly named as CEC in Spanish (Comités Ético-Científicos)

Decree N° 494 of 1999, issued by the Ministry of Health created an entity called Ethical-Scientific Evaluation Committee which shall be in charge of reviewing the clinical investigation protocols. The regulation transfers to the CEC these functions given in the past to the Hospital Ethics Committees.

The CECs are divided in areas and regions, depending on the Health Service involved.

For those Health Services with no Ethical-Scientific Evaluation Committee, the Health Service Board must appoint a Reference Ethical-Scientific Evaluation Committee.

CEC will undergo an accreditation process (Technical Norm N°151 & DS 114 to the law 20120, Article 10).
1. Regulatory Bodies (CEC)

CEC SS Zona Norte – Coquimbo (Zona Norte: Norte Grande y Norte Chico: Sites located in XV Región [Arica y Parinacota] and from the I to the IV Region [Iquique to Coquimbo])

CEC SS Viña-Quillota (Zona Centro: Sites located in V Region from Viña del Mar to Los Vilos)

CEC SS Valparaíso-San Antonio (Zona Centro: Sites located in V Region from Valparaíso to San Antonio)

CEC Zona Centro: Región Metropolitana – Santiago (6)
CEC SSM Oriente; CEC SSM Occidente;
CEC SSM Sur; CEC SS M Norte; CEC SS M Central;
CEC SS Metropolitano Sur Oriente; CEC SS M Sur Occidente
CEC Pediátrico SSM Oriente

CEC SS O’Higgins (Sites of the VI Region)
CEC SS del Maule (Talca)

CEC H.G.G.B. of Concepción (Zona Sur: Sites located in VIII Region: including Concepción and Talcahuano)

CEC SS Araucanía Sur (Zona Sur: Sites of the IX Región: between Temuco and Victoria)

CEC SS de Valdivia (Zona Sur, Patagonia Norte y Patagonia Sur: Sites of the X to the XII and XIV Region Valdivia: Region de los Lagos y Ranco)
2. Submission process: Document Requirements

**CEC /LEC Submission (main documents):**
- Protocol (English & Spanish)
- Executive protocol summary
- Investigator Brochure
- Informed Consent Form
- Any patient’s material *
- Insurance Certificate
- Any other document part of the dossier
- Placebo justification letter (if applicable)
- Submission Letter from Investigator
- CV of Principal Investigator
- Site’s director approval letter
- AoR of the payment fee.

**Regulatory Submission (main documents):**
- Protocol (English & Spanish)
- Investigator Brochure (English & Spanish)
- Informed Consent Form & Assent (Spanish approved versions dated, signed & stamped)
- Delegation Letter (for CROs)
- First CEC approval letter
- Letter from the Health Service to the CEC (if applicable)
- Labeling Text [Circular N°4] & storage condition
- Description and amount of IP to be imported
- Data from the Depot and Distributor
- Valid GMP certificate of the IP manufacturer
- Manufacturing process (biological products)
- PNI (National Immunization Program) approval letter (in case of vaccines)
- Simple statement of the petitioner
- CV of Principal Investigator
- Lab certificates (Local or International Labs)

* Only required by the ECs

Site’s Director approval letter is also required after CEC/LEC approval but not required for RA submission
To take into consideration:

- Placebo arm is authorized when no treatment is available and in case of Add-on studies. A justification letter is always required.
- Phase IV trials could be notified to the RA if no IP importation is required.
- Clinical Trials of Medical Devices only require EC approval (MoH is not applicable).
- The RA has an expedited review process for seasonal studies (e.g. vaccines) and should be requested formally with the reason for this expedited review (approval timelines about 3 weeks).
- Concomitant medications are not mandatory to be paid. Depending on the study design, it is recommendable to be covered e.g. cancer trials.

After Site’s Selection:

- The site’s Director pre approval letter is mandatory for most of the EC as part of the initial dossier, therefore it should be requested as soon as the site is selected.
- A power point presentation must be provided at the beginning as the ECs request to the principal investigator to perform a brief presentation of the protocol (some CEC request it in Spanish).
2. Submission process: Recommendations

Insurance Certificates:

- Are only required by the Ethics Committees (EC).
- The global insurance certificate is acceptable, nevertheless few CECs request in addition a local representative for the insurance company and the copy of the insurance policy.
- Insurance certificate is not required by the ISP (ANAMED), according to Circular N°4.
- Any update should be notified by the investigator to his/her EC.

Contracts with the Sites:

- The type of the contract template should be identified since the beginning as there are tripartite and bipartite contracts being used in Chile. Most of the sites prefer to have a third party payee which should be reviewed in advance.
- Some institutions proceed with the contract review/execution after local EC approval.
- Few institutions request to have the pharmaceutical company signing the contract instead of the CRO.
2. Submission process & timelines

Dossier preparation

4 weeks

EC approval

8-12 weeks

*16 weeks

ISP Approval

6-8 weeks

Import Process

3 weeks

Total approval time: 18 - 24 weeks (3.5 - 6 months)

Local EC ~ Central EC: 8-12 weeks (in parallel)
MoH: 6-8 weeks (*including Import License) + Import process: 3 weeks
2. MoH submission review process

MOH submission for obtaining the study approval & Import License

- Clinical Trials that require to import an investigational product (IP) must request this importation to the MoH with at least 1 CEC approval.

- This applies essentially to clinical trials Phase I to IV.

- MoH approval includes the import license (IL), therefore IP shipment could start once it is obtained.

- Studies that would not require an IP importation do not need to be notified to the MoH (e.g. observational studies), but must be approved by the corresponding Ethics Committees.

- Submissions are performed electronically through GICONA (*mandatory with few exceptions since May 2010, Circular N°03 /2010*)

http://www.ispch.cl/anamed/subdeptoregistro/seccion_estudios_clinicos/info_gral
2. MoH submission review process - GICONA

Sistema Informático de Tramitación en Línea

Acceso a portal de usuarios

Password → ID Number
2. MoH submission review process - GICONA

GICONA = Sistema de Gestión de Información de Control Nacional
2. MoH submission review process - GICONA

- **Artículo 21 letra c**: Initial Submission New study & Amendments to the Initial Resolution.
- **Notificación de Eventos Adversos Serios Relacionados e Inesperados Nacionales**: Notification of local SAEs related and unexpected (SUSARs).
- **Notificaciones de cambios menores en Estudios Clínicos**: Notifications of minor changes in Clinical Trials.
- **Rectificaciones**: Corrections.
2. MoH submission review process - GICONA

For both type of Submissions a Resolution is issued by ANAMED
2. MoH submissions along the study

The following submissions do not require ISP approval, should be notified to the ISP within 15 calendar days (following CEC approval):

- Change of Principal Investigator
- Inclusion of new research site
- Update of Investigator Brochure
- Modification of Informed Consent Form
- Amendment to Protocol that does not involve the IP

The following requests require ISP (ANAMED) approval, a resolution is issued (amendment to the IL):

- Amendment to clinical trials that involve the IP
- Quantity Extension of IP to be imported
- New Product(s) to be imported
- Change or extension of storage depot
- Change or extension of procedence
- Change of the owner of the IL

Ref. Circular N°4
2. MoH submission review process - GICONA

Additional Sites

- Additional sites are notified once the initial MoH approval is received.

- For additional sites a complete dossier is requested by most of the CEC with few exception (e.g. CEC SSM Oriente which only requests ICFs, CVs, Director’s approval letter)

- Most of the CECs require a fee per site, this should be reviewed by each case (e.g. CEC SSM Oriente does not require any additional payment)

MoH Required documents / information (web notification):

- New Site’s Name
- Name of Principal Investigator (PI)
- Curriculum vitae (CV) of PI
- CEC approval Letter
- Informed Consent Form stamped, signed and dated
- Any other specific documents (e.g. CEC transfer letter)
Amendments – Protocol & ICF

Amendments in general are notified to the MoH after CEC approval, e.g.
- Amendments to the Informed Consent Form
- Amendment to Protocol that does not involve the IP

Amendments could be implemented after CEC approval

Amendments to clinical trials that involve the IP (IL amendments) require MoH approval (a fee must be paid)
- CEC and MoH submission are sequential

Documents required:
- Amendment + summary of changes
- CEC approval letter (sequential process)
- Informed Consent stamped and dated by the CEC

In case of safety amendments, these are notified to the MoH and process could be done in parallel. English submission is feasible.
2. MoH submissions along the study

**Other Notifications**

- Site is opened (*when informed consent process could start, usually Site Initiation Visit*) within 15 calendar days.

- Periodic Annual Reports (following CEC notification), within 15 calendar days.

- Site closure should include CEC notification & Drug Accountabilities (*Inventory Logs*); notification within 15 calendar days.

- In case of early closure, the reasons for this closure should also be stated.

- Deviations related to the IP are recommendable to be notified (*corrective actions should also be informed*).

- Deviations that put on risk the patient’s safety should also be notified, although there is no specific regulation in regards to this item.

- Final study report (*synopsis*) could be notified in English.
2. MoH submissions along the study

http://www.ispch.cl/anamed/subdeptoregistro/seccion_estudios

NOTIFICACIONES DE CAMBIOS MENORES EN ESTUDIOS CLINICOS

Las siguientes notificaciones relacionadas al protocolo de investigación y/o anexos, deben ser enviadas al Instituto en un plazo no mayor de 15 días corridos, una vez en conocimiento o aprobadas por el Comité Ético-Científico correspondiente, adjuntando la carta de aprobación de dicho comité (cuando corresponda):

- Enmienda al protocolo, que no involucre al producto farmacéutico en investigación.
- Cambio de Investigador principal.
- Informes de avances anuales, por cada centro, indicando cantidad de sujetos enrolados, ocurrencia de eventos adversos serios y violaciones/desviaciones de protocolo.
- Incorporación de nuevo centro de investigación.
- Apertura o inicio de cada centro de investigación.
- Actualización de Manual del Investigador.
- Modificación del Formulario de Consentimiento informado (nuevas versiones).
- Cierre del estudio clínico en el país, indicando un informe resumen por cada centro (sujetos enrolados, eventos adversos serios, violaciones/desviaciones de protocolo) o carta de cierre de centro enviada por el investigador al Comité Ético-Científico respectivo, y la cantidad final de productos farmacéuticos importados y/o fabricados, utilizados, no utilizados y destruidos (si aplica).
- Resumen o sinopsis final del estudio clínico a nivel global.

Estas notificaciones se deberán ingresar a través del módulo Notificaciones de Cambios Menores del sistema informático GICONA, disponible en la página Web de este Instituto http://www.ispch.cl/sistema-informatico-de-tramitacion-en-linea, adjuntando los antecedentes correspondientes y sin pago de arancel.
2. MoH submission review process - GICONA

<table>
<thead>
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<th>Nº Referencia Estudio Clínico</th>
<th>Obtener</th>
<th>Buscar</th>
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<tbody>
<tr>
<td>Nº Res. Apr. EC</td>
<td></td>
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<tr>
<td>Nº Protocolo</td>
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<tr>
<td>Título Estudio Clínico</td>
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<tr>
<td>Descripción de la Notificación</td>
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<td>Tipo de Notificación</td>
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<td></td>
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<tr>
<td>Documentación Adjunta</td>
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</tr>
</tbody>
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*Image: GICONA Sistema de Gestión de Información de ANAMED*

- **Evento**
  - Enmienda que no afecta al medicamento
  - Nuevo Centro
  - Actualización del Formulario de Consentimiento Informativo
  - Actualización del Manual del investigador
  - Cambio de Investigador
  - Cambio de Fabricante
  - Otro

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*Images: Example screen of GICONA system showing submission process and notification options.*
2. MoH submission review process - GICONA

Correction Request to the Resolution
3. Import Process – Use & Disposition

Original IL is an "Umbrella IL" for the duration of the study, however, each shipment requires an additional approval “Authorization for Use and Disposition”.

Use and Disposition: Is obtained for each importation and is performed by using GICONA (web page of the ISP).

The "Use and Disposition" application requires:
- The IL (scanned copy)
- The Comercial Invoice (scanned copy)
- The AWB (Air Way Bill of the shipment)
- A “Certificate of Customs Destination” (CDA = Certificado de Destinación Aduanera) which is issued electronically

CDA is used for custom clearance (IP could be sent from the custom to the depot).

Use and Disposition authorization is issued per importation (within 10 working days or less) and is required to dispatch the IP to the sites.
3. Import Process – Use & Disposition

**USO Y DISPOSICIÓN**
- Solicitud de Certificado de Destinación Aduanera y Autorización de Uso y Disposición
- Aclaraciones requeridas por el ISP a Solicitudes de Uso y Disposición en trámite
- Aclaraciones a Resoluciones de Uso y Disposición (Aprobadas o Rechazadas)
- Modificaciones a CDA y Solicitud Uso y Disposición sin DIN
- Envío de Protocolo de Análisis

**CONSULTAS**
- Listado de Certificados de Destinación Aduanera
- Listado Resoluciones de U y D
3. Import Process – Use & Disposition

GICONA
Sistema de Gestión de Información de ANAMED

<table>
<thead>
<tr>
<th>Mi GICONA</th>
<th>QUINTILES CHILE</th>
</tr>
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<tbody>
<tr>
<td>Proceso</td>
<td>Autorización UyD</td>
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<tr>
<td>Arancel</td>
<td>4111031</td>
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<tr>
<td>Prestación</td>
<td>AUTORIZACIÓN DE USO Y DISPOSICIÓN, LEY 18.164 (POR PRODUCTO)</td>
</tr>
</tbody>
</table>

**Use & Disposition GICONA**
3. Import Process – other information

- Lab kits and study materials do not require an IL to be imported:
  - Laptops, any equipment (ECGs machines, electrodes, thermometers, etc.)
  - CRFs, paper documents
  - Supplies to be used as gifts to the patients

- **Syringes – Needles – Condoms – Gloves** are considered medical devices that requires import permit (its application is done separately) - *Vacutainers do not belong to this item*

- A door-to-door shipment is allowed for these supplies (could be sent directly to the sites or a depot)

- An invoice value over 1000 USD, requires a tax payment and release from customs (*a broker is used*)

- Invoices are recommendable to be reviewed before each shipment

*No Export License (EL) is required for exporting biological samples, i.e. each study site could export the biological samples collected BUT in case of Study Medication or Comparators an Export Permit is required*
3. Import Process – other information

**Syringes – Needles** [D.S. N°1887/2007] & **Condoms – Gloves** [D.S. N°342/2004] are considered medical devices that require additional quality controls and therefore their importation is under mandatory control. The recommendation is to buy them locally.

If an importation of these supplies is done the following requirements should be considered:

- Importation could start after initial RA approval
- Use & Disposition for the devices and their certification process are requested once arrived at the country.
- Invoice must meet local & international requirements (commercial name of product, lot number, total quantities of units per item, manufacturer name, and country, country of origin and AWB).
- Additional certificates from the vendor should be provided (e.g. System Certification ISO or GMP provider; Export License issued by the regulatory authority or MoH of the country of origin).
- The certification process per item could cost about $6000 USD.
4. Safety Reporting – MoH Submission Flow

ONLY SUSARS
(Suspected Unexpected Serious Adverse Reaction) for IP and comparators

Notification for phase 1-3 trials:
- Chilean SUSARs by GICONA
- International SUSARs & Periodic Safety Reports (DSUR) by e-mail to the Clinical Trial Unit

15 calendar days or 7 calendar days (results in death, is life-threatening + FU at Day 8)

To notify the CIOMS Form (plus Spanish translation)

INTERNATIONAL

Notification for phase 4 and registered comparators:
- Chilean SUSARs, International SUSARs & Periodic Safety Reports (DSUR) by e-mail to PHV department.

Every 2 months (after MoH study approval)

To notify only SUSARs related to the study protocol by using an excel sheet tracker (Forms available at http://www.ispch.cl/)

Notify the Periodic Safety Reports annually & at study end (it must include the risk – benefit assessment)

Res. 0441 13Feb2012
The Inspections to Clinical Trials could be ordinary or extraordinary

Ordinary Inspections are notified by e-mail at least 10 working days before the visit to the site.

Extraordinary Inspections are notified by e-mail within 24h-48h before the visit to the site.

The following information is requested by e-mail:

- Number of subjects screened, enrolled and randomized
- Serious Adverse Events (SAEs) at the site
- List of Study Staff (profession and delegated function)
- Retrieval and/or Destruction of the investigational product (If applicable)
- Site opening date (when informed consent procedure could start)
- Local or International Clinical Laboratories involved (Name)
5. MoH Inspections - Clinical Trial Unit

- A checklist is provided with the items that will be inspected.
- Site’s facilities, equipment, investigational product are being inspected as well as all documentation related to the study.
- The commitment of the Principal Investigator and the study staff as well the CVs, GCP training within other documents are being reviewed.
- At the end of the inspection, the inspectors will provide written minutes of the observations and findings solved and not solved during the inspection.
- Any finding should be clarified /responded through GICONA within 10 working days (once report is retrieved).
- An acknowledgement of receipt from the leading inspector is sent by e-mail to the applicant "satisfactory receipt and acceptance of the measures taken".
- Please refer to the Resolution N°1847: Inspection Guide.
6. Clinical Trials published at the ISP web page

http://www.ispch.cl/
7. N° Estudios Clínicos Chile: 2002-2011

http://www.ispch.cl/
8. Advices of New Procedures

- As per law 20584, article 28: “In cases in which scientific research is carried out with the participation of people with psychic or intellectual disability that have the capacity to express their will and that have given an informed consent, apart from the corresponding ethics-scientific assessment, the authorization of the competent Health Authority will be necessary, and the express manifestation of being willing to participate on the part of the patient and his/her legal representative”. It was clarified during the last workshop with the Health Authorities on 31 Jul 2013, that after CEC approval is received, the approval letter and stamped Informed Consent Form should be sent to the SEREMI (separate MoH department different from ISP) for final validation. Process to be performed in parallel to the ANAMED submission. New process still under review!

- CEMEIS is providing support for the CEC accreditation which will also be under the SEREMI responsibility.

- Decree N°114 & Technical Norm N°57 are under review.
Questions & Answers

mafalda.gimenez@quintiles.com

Thank You
Gracias
Obrigado