Approccio del laboratorio analisi alla diagnostica delle malattie autoimmuni sistemiche (questionario)

Proposta Phadia-ThermoFisher (fine luglio '12)

- definizione progetto (ago-set '12)
- accettazione proposta (direttivo ristretto, ottobre '12)
- formalizzazione (novembre '12)

SCOPO: raccolta informazioni sull'**approccio del lab analisi nei confronti delle richieste di dosaggio ANA e anticorpi correlati. Il questionario è parte di un progetto promosso dall'"*European Autoimmunity Standardisation Initiative*" (E.A.S.I.,** www.easi-network.com), allo scopo di "fotografare" e confrontare le realtà nei diversi paesi Europei, con l'obiettivo di individuare i percorsi più adeguati per l'inquadramento e la gestione dei pazienti

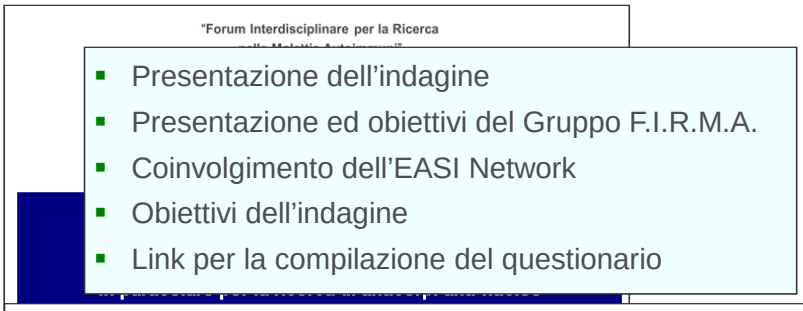
RUOLI:

- *Leader* del progetto EASI
- *Collaborator* per FIRMA Meroni e Radice
- *Coordinator* Tozzoli (Presidente FIRMA)

- traduzione e rielaborazione delle domande presenti nel questionario già utilizzato, per adeguarle alla realtà italiana, pur mantenendo l'assetto originale (dic '12)
- preparazione elenco destinatari (incrocio di diverse *mailing-list* e conoscenze personali, Bianchi-Radice, gen '13)
- elenco definitivo e costruzione *mailing-list* (> 600 destinatari, "ripulitura" successiva (Bianchi-Radice, feb '13)
- realizzazione del questionario "grezzo" (Sormani, Bianchi)
- prove di funzionalità (risposte obbligatorie, reinvio al paragrafo successivo, salvataggio dati inseriti e recupero degli stessi), aspetto grafico, modalità di recupero dati...) (Sormani-Bianchi-Radice, feb '13)
- prove di funzionalità sulla base delle modifiche apportate, definizione aspetto grafico e modalità di invio (Sormani-Radice-Glionna-Trezzi, marzo '13)

invio mail con link al questionario

(segreteria@gruppofirma.com 30.04.13)



- informativa sulla privacy
- 68 domande a risposta multipla
- 5 sezioni
- campi obbligatori
- invio automatico alla domanda/sezione successiva
- la compilazione può essere interrotta (i dati vengono salvati)
- necessità di continuare la compilazione dalla stessa postazione

APPROCCIO DIAGNOSTICO DELLE MAIS NEI LABORATORI ITALIANI

FASE 2

- **Raccolta delle risposte** al questionario tramite *software* online **www.surveymonkey.com**
- analisi statistica per mezzo dello stesso strumento di indagine, con accesso dedicato e riservato a F.I.R.M.A
- **presentazione risultati al congresso di Dresda (set '13)**
- presentazione dati (modalità da definire) al congresso SIMEL (ott 13)
- presentazione in corso di altri eventi (da definire)
- **pubblicazione** dati su rivista di settore
- **progetto realizzato con il contributo non condizionante di Thermo Fisher Scientific, ImmunoDiagnostics Division, Phadia S.r.l.**

11th DRESDEN SYMPOSIUM ON AUTOANTIBODIES
Dresden, September 1-4, 2013

AUTOIMMUNITY DIAGNOSTIC STRATEGIES
(ANA, anti-dsDNA, anti-ENA) IN ITALIAN CLINICAL LABORATORIES

Radice A[1], Bianchi L[2], Glionna S[2], Trezzi B[2], on behalf of Forum Interdisciplinare per la Ricerca sulle Malattie Autoimmuni (F.I.R.M.A.)
[1]Microbiology Inst, [2]Clinical Immunology & Renal Unit, San Carlo Borromeo Hospital Milano.

INTRODUCTION: ANA and related antibodies are fundamental for the diagnosis of autoimmune diseases. Since the request for autoantibodies is increased, new techniques, as well as testing-strategies, have been recently developed.

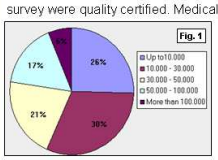
AIMS OF THE STUDY: The survey is a project of the "*European Autoimmunity Standardisation Initiative*" (E.A.S.I., www.easi-network.com), with the financial support of Phadia S.r.l., part of Thermo Fisher Scientific, aimed to investigate the daily practice in the different European countries, to find appropriate tools for managing systemic autoimmune rheumatic diseases (SARD).

METHODS:

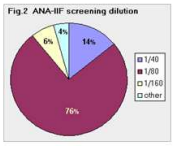
- a 68 multi-choice questions questionnaire was sent to more than 600 laboratory specialists, representative of 444 labs;
- the questionnaire was introduced by an e-mail, with the link to a web-site for the drawing up;
- returned polls from Labs performing Autoimmune Diagnostic Testing were identified and statistically evaluated by using the online software Survey Monkey (www.surveymonkey.com).

PRELIMINARY RESULTS

30% of the questionnaires was completed: most (74%) were from public and the remaining from private or academic Institutions, 60% of the laboratories were of large dimension (autoimmune tests performed yearly shown in Fig.1). Autoimmunity was only rarely independent, more often it was part of one of the major specialties (Clin. Biochemistry 44%, Central Lab 19%, Clin. Immunology 13%, Microbiology 10%). 70% of the laboratories taking part to the survey were quality certified. Medical doctors (50%) or biologists (46%) were in charge for the autoimmune diagnostics.



ANA-testing: ANA were detected by IIF on HEp-2/HEp-2000 in more than 90% of the centers, sometimes followed by a 2nd assay (screening dilutions in Fig. 2).
IIF evaluation was done by two or more specialists in up to 60% of the labs.
Interestingly, in only two centers a digital image analysis system, followed by specialist control, was used. 91% of the +ve samples were diluted until 1:640 (36%), 1:1280 (31%), 1:2560 or more (33%). Recognized fluoroscopic patterns are listed in Fig. 3.
Titers & patterns were almost always reported to the clinicians.
Samples with exclusively cytoplasmic reaction were generally referred as "ANA negative, presence of cytoplasmic staining pattern".



anti-dsDNA were detected with the most "appropriate" assay, and more than one method was used in two-third of the labs (Fig. 4a, 4b). Discordant results were reported as described in Fig. 5.

Clinical and Experimental Rheumatology 2014; **32:** 000-000.

From ANA-screening to antigen-specifity: an EASI-survey on the daily practice in European countries

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Abstract

Objective

One of the main goals of the European Autoimmunity Standardisation Initiative (EASI) is the harmonisation of test-algorithms for autoantibodies related to systemic autoimmune rheumatic diseases (SARD).