¿Cómo puede una institución del sector salud, convertirse en un centro de investigación reconocido?

Jorge Hernando Donado Gómez MD MSc.
jdonado@hptu.org.co

EL HOSPITAL CON ALMA
Pablo Tobón Uribe

Agenda

1. Direccionamiento estratégico
2. Política de calidad
3. Reclutamiento
4. Ética

Agenda

1. Direccionamiento estratégico
2. Política de calidad
3. Reclutamiento
4. Ética

EL HOSPITAL CON ALMA
Pablo Tobón Uribe

Aspectos Generales

Fundación Privada

Institución sin ánimo de lucro

Hospital Universitario

Hospital de alta complejidad

44 años de servicio

EL HOSPITAL CON ALMA
Pablo Tobón Uribe

El Hospital en cifras - 2013

1,932 Colaboradores

13,690 Egresos

371 Camas (77 cuidado critico)

81,589 Estudios Radiológicos

11,785 Cirugías

Ejecución presupuestal
$ 272 mil millones

785,684 Ex. de Laboratorio

49,533 Urgencias

EL HOSPITAL CON ALMA
Pablo Tobón Uribe

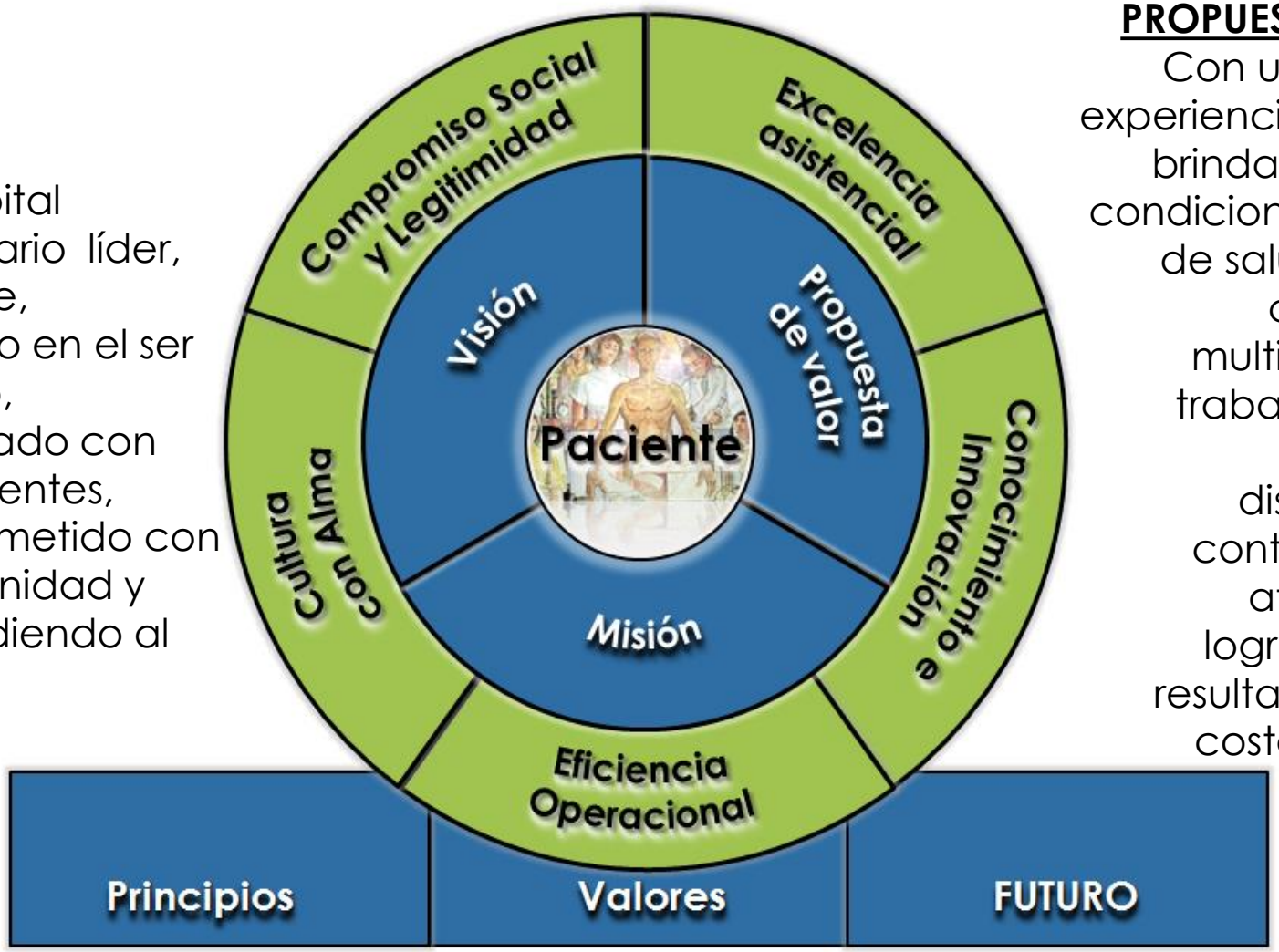
Planteamiento Estratégico 2014 - 2020

MISIÓN

Brindar la mejor atención en salud de alta complejidad y contribuir a la generación y transmisión del conocimiento en el marco del humanismo cristiano

VISIÓN

Ser Hospital universitario líder, referente, centrado en el ser humano, coordinado con otros agentes, comprometido con la comunidad y trascendiendo al mundo

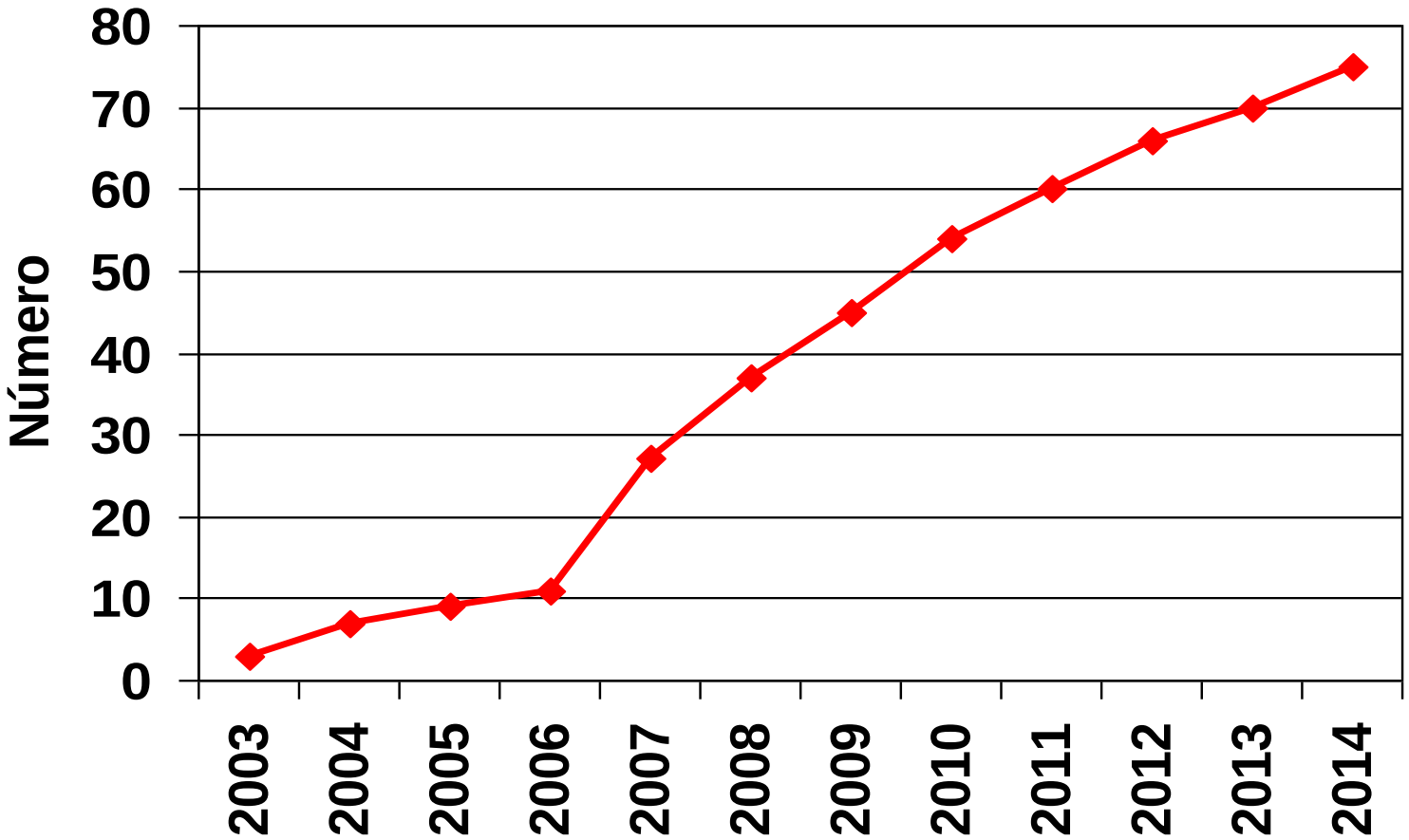


PROPUESTA DE VALOR

Con una excelente experiencia de servicio, brindar soluciones a condiciones complejas de salud, mediante conocimiento multidisciplinario y trabajo en equipo, adecuada disponibilidad y continuidad de la atención, para lograr los mejores resultados clínicos a costos equitativos

Fecha de vigencia 13/01/2013

Evolución de protocolos de desarrollo de fármacos



EL HOSPITAL CON ALMA
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Agenda

1. Direccionamiento estratégico
2. Política de calidad
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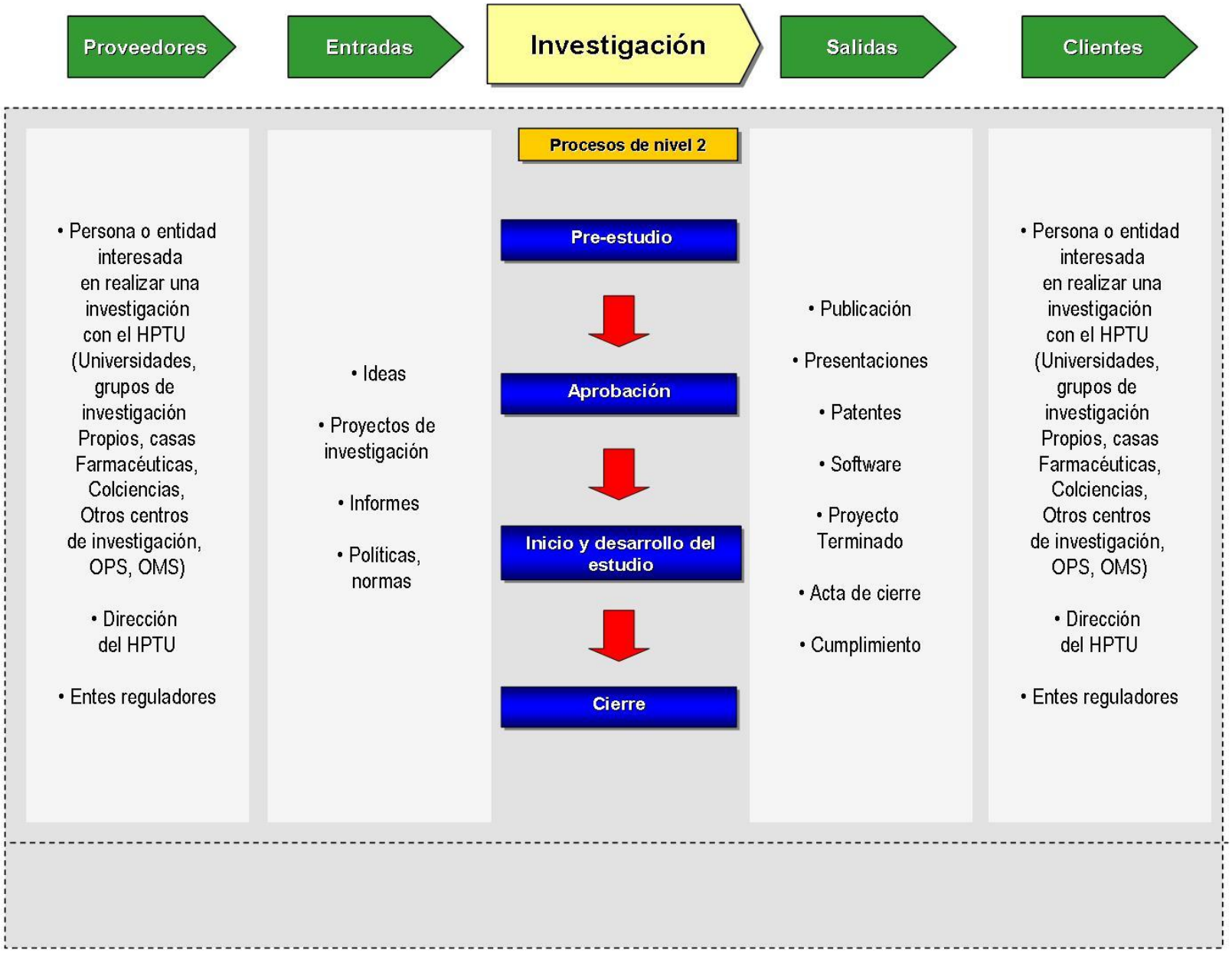
4. Ética

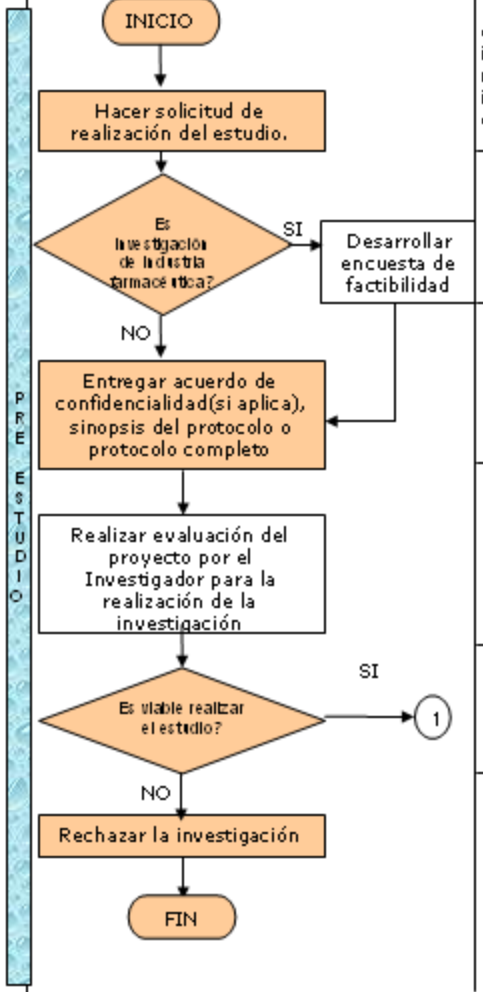
Interrelación de Procesos


Proveedores
Entradas
Investigación
Salidas
Clientes
• Persona o entidad interesada en realizar una investigación con el HPTU (Universidades, grupos de investigación Propios, casas Farmacéuticas, Colciencias, Otros centros de investigación, OPS, OMS)
• Dirección del HPTU
• Entes reguladores
• Ideas
• Proyectos de investigación
• Informes
• Políticas, normas
Procesos de nivel 2
Pre-estudio
Aprobación
Inicio y desarrollo del estudio
Cierre
• Publicación
• Presentaciones
• Patentes
• Software
• Proyecto Terminado
• Acta de cierre
• Cumplimiento
• Persona o entidad interesada en realizar una investigación con el HPTU (Universidades, grupos de investigación Propios, casas Farmacéuticas, Colciencias, Otros centros de investigación, OPS, OMS)
• Dirección del HPTU
• Entes reguladores


Pre-estudio
Encuesta de factibilidad
Estudio de viabilidad
Aprobación
Evaluación por parte del Comité de Investigaciones y Ética en Investigaciones
Formalización del contrato o acta de compromiso
Inicio y desarrollo del estudio
Implementación del proceso investigativo
Desarrollar y entregar informe parcial del estado del estudio
Cierre
Notificar cierre del estudio
Divulgación de resultados

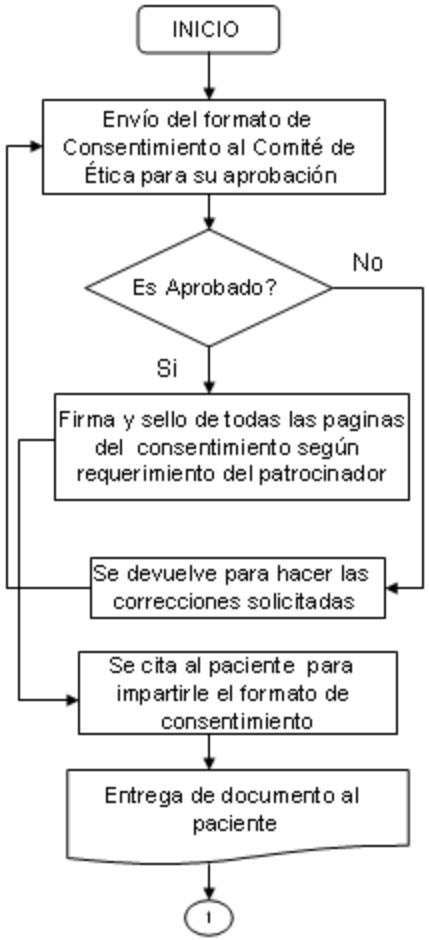
Procedimiento específico Investigación

ESTANDAR DE PROCESO /INVESTIGACIÓN



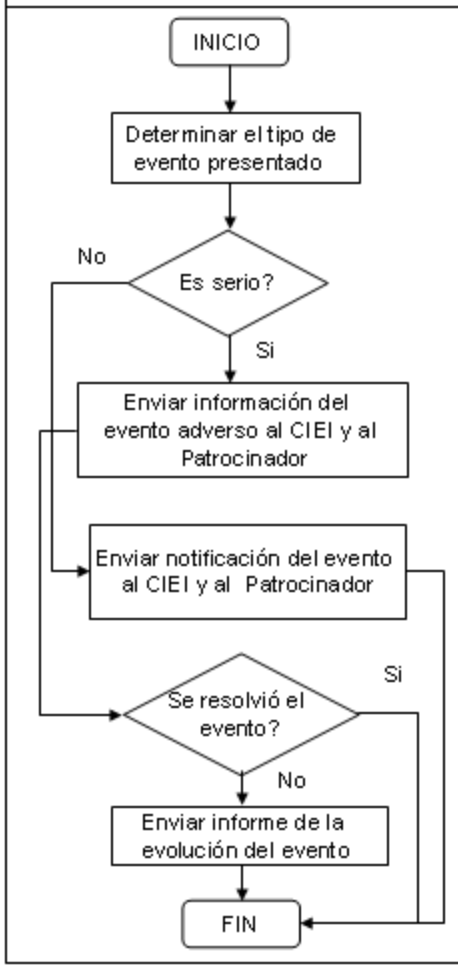
FLUJOGRAMA	QUIÉN	CUÁNDO	DÓNDE	POR QUÉ	CÓMO
INICIO	Persona o entidad interesada en realizar una investigación en el HPTU.	Haya interés en realizar la investigación en el HPTU	Oficina jefe de la unidad de investigación.	Se debe dar conocimiento a la institución del deseo de realizar el estudio para revisar la viabilidad de su realización.	Carta, correo electrónico, llamada telefonica o contacto personal dirigida al jefe de la unidad de investigaciones.
Hacer solicitud de realización del estudio.	El jefe de unidad y la Persona encargada del área clínica donde se va a realizar la investigación.	Haya interés en realizar la investigación en el HPTU	Área donde se va a realizar la investigación y unidad de investigaciones	Es necesario que el patrocinador verifique que el sitio es apto para realizar la investigación	Suministrando los datos requeridos por el patrocinador. No se deja registro en el sitio.
Es investigación de industria farmacéutica? SI → Desarrollar encuesta de factibilidad; NO	Persona o entidad interesada en realizar una investigación en el HPTU.	Con la carta de Solicitud.	Oficina jefe de la unidad de investigación.	Se debe tener conocimiento del contenido del estudio y analizar su viabilidad.	Acuerdo, Sinopsis del protocolo completo o ficha técnica. Investigaciones sin riesgo no requieren protocolo completo, solo ficha técnica.
Entregar acuerdo de confidencialidad(si aplica), sinopsis del protocolo o protocolo completo	Jefe unidad de investigación e Investigador delegado	Una vez se haya establecido al tener el acuerdo de confidencialidad, la sinopsis y el protocolo completo.	Unidad de Investigación.	Seleccionar propuesta viable .	Por análisis de los documentos entregados, mediante lista de chequeo de evaluación del protocolo por el investigador.
Realizar evaluación del proyecto por el Investigador para la realización de la investigación	Jefe unidad de investigación e Investigador delegado	Una vez conocido el tipo de estudio	Unidad de Investigación.	Se debe seleccionar protocolos de enfermedades comunes en los pacientes del hospital.	Revisando criterios de selección.
Es viable realizar el estudio? SI → 1; NO	Jefe unidad de investigación e investigador potencial.	Después de haber hecho el análisis y evaluación del proyecto por el Investigador.	Unidad de Investigación.	Por su naturaleza el hospital no tenga los recursos para desarrollar la investigación .	Analizando los documentos y por medio de comunicación verbal al patrocinador.
Rechazar la investigación → FIN					

ESTANDAR DE PROCESO /CONSENTIMIENTO INFORMADO DEL ESTUDIO, FARMACOCINÉTICO Y GENÉTICO



	QUIÉN	CUÁNDO	DÓNDE	POR QUÉ	CÓMO
	Investigador o subinvestigador	Antes de iniciar el estudio	Comité de Investigaciones y ética en investigaciones	Se debe verificar la redacción y contenido del documento	Formato físico y electrónico
		En el momento de la revisión por el CIEI	Comité de Investigaciones y ética en investigaciones	Garantizar que sea legible por el sujeto y que cumpla con la normatividad	Formato físico
	Presidente CIEI	Una vez sea aprobado	Oficina presidente del CIEI	Para tener respaldo de la aprobación	Formato físico
	Coordinador de investigación	Cuando el CIEI da respuesta	Unidad de investigaciones	Se debe informar al patrocinador los cambios que se deben realizar	Formato físico o electrónico
	Coordinador de investigación	Antes de ingresar al estudio	Unidad de investigaciones	Se debe brindar toda la información al paciente	Llamada telefónica
	Investigador o subinvestigador	Antes de ingresar al estudio	Unidad de investigaciones	El sujeto de investigación debe contar con la información necesaria para decidir	Formato físico

ESTANDAR DE PROCESO /REPORTE DE EVENTOS ADVERSOS



	QUIÉN	CUÁNDO	DÓNDE	POR QUÉ	CÓMO
	Investigador o subinvestigador	Cuando obtiene información del suceso	Unidad de investigaciones	Se debe tener claro el proceso a seguir	En carta dirigida al CIEI
	Investigador o subinvestigador	Durante las primeras 24 horas de conocerse el evento.	CIEI y Patrocinador	Se debe brindar la información más relevante del evento para que el patrocinador lo reporte al INVIMA	En carta dirigida al CIEI
	Investigador o subinvestigador	En el informe anual que se presenta al CIEI y al patrocinador en los quince días después de ocurrido	CIEI y Patrocinador	Porque se debe notificar al CIEI y al Patrocinador todo lo ocurrido durante el estudio	En carta de informe anual dirigido al CIEI
	Investigador o subinvestigador	Cada quince días después de reportado.	CIEI y Patrocinador	Para informar constantemente de la evolución del evento hasta que se resuelva	En carta dirigida al CIEI

Competitividad

Buenas Prácticas Clínicas en Investigación por el INVIMA Resolución 2011035725 del 20 de septiembre de 2011

Realización de Investigaciones en Salud por el ICONTEC NTC-ISO 9001:2008, registro número CO-SC1290-16 del 27 de octubre de 2008

EL HOSPITAL CON ALMA
Pablo Tobón Uribe

IQNet

ISO 9001

icontec

ICONTEC Certifica que el Sistema de Gestión de la Calidad de:
ICONTEC Certifies that the Quality Management System of:

HOSPITAL PABLO TOBÓN URIBE

Calle 78B No. 69-240 Medellín, Antioquia, Colombia

ha sido evaluado y aprobado con respecto a los requisitos especificados en:
has been assessed and approved based on the specified requirements of:

ISO 9001:2008 - NTC-ISO 9001:2008

Este Certificado es aplicable a las siguientes actividades:
This certificate is applicable to the following activities:

Realización de investigaciones en salud

Execution of health research

Esta aprobación está sujeta a que el sistema de gestión se mantenga de acuerdo con los requisitos especificados, lo cual será verificado por ICONTEC
This approval is subject to the maintenance of the management system according to the specified requirements, which will be verified by ICONTEC

Certificado SC 1290-16
Certificate

Fecha de Aprobación: 2002 12 13
Approval Date

Fecha Última Modificación: 2011 10 28
Last Modification Date

IQNet®

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

IQNet and
ICONTEC
hereby certify that the organization

HOSPITAL PABLO TOBÓN URIBE

Calle 78B No. 69-240 Medellín, Antioquia, Colombia

for the following field of activities:

Realización de investigaciones en salud

Execution of health research

has implemented and maintains a

Quality Management System

which fulfills the requirements of the following standard

ISO 9001:2008

Issued on: 2011 10 27
Validity date: 2014 10 26

Registration Number: CO-SC 1290-16

IQNet

Michael Drechsel
President of IQNet

Fabio Tobón
Executive Director of ICONTEC

icontec

http://www.aahrpp.org/

EL HOSPITAL CON ALMA
Pablo Tobón Uribe

http://www.aahrpp.org/

EL HOSPITAL CON ALMA
Pablo Tobón Uribe

Programa de Protección de Investigación en Humanos

Conformado por tres dominios:

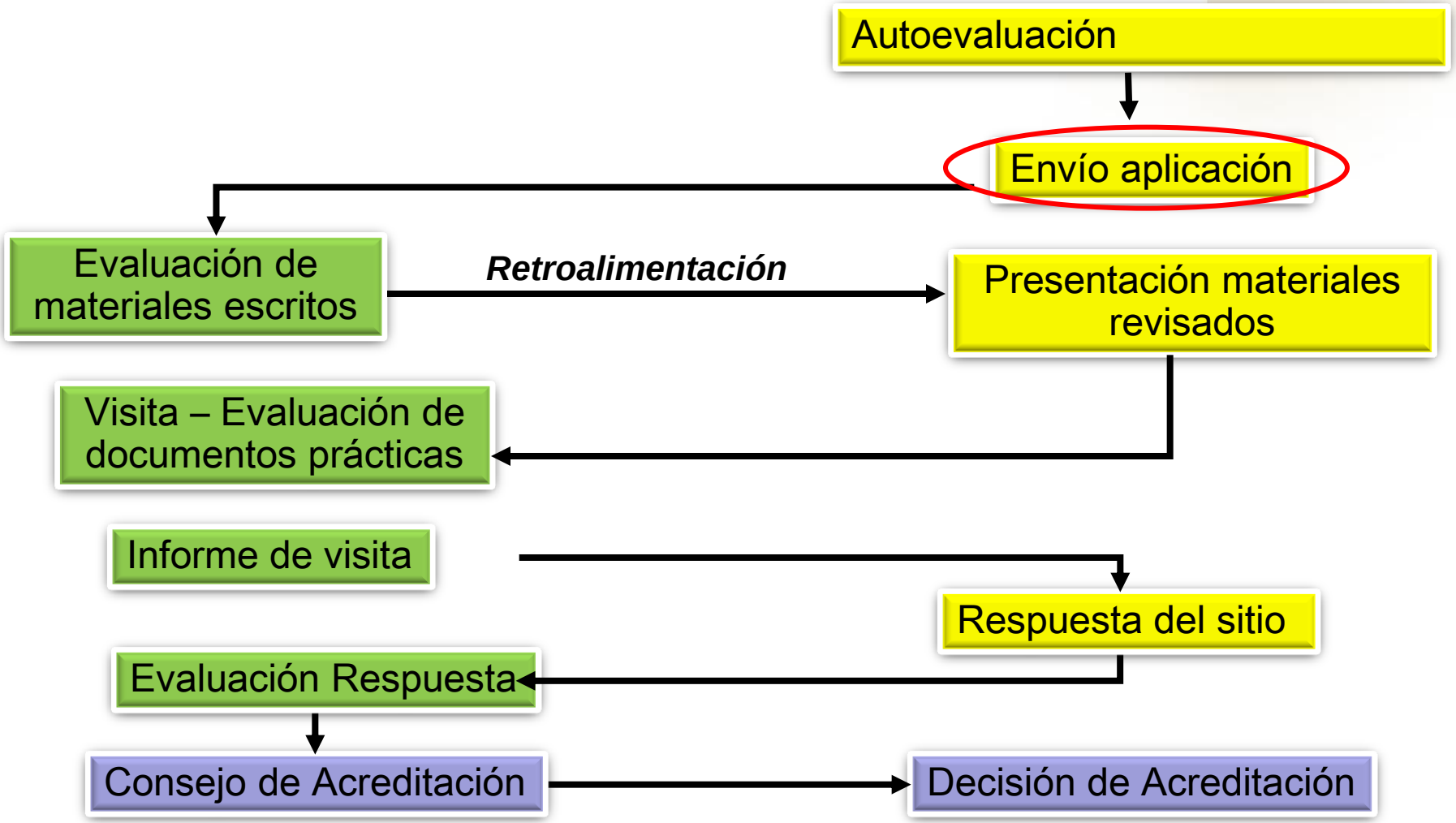
Dominio 1: Organización

Dominio 2: Comité de Ética en Investigación

Dominio 3: Investigadores y Equipo de Investigación

Programa de Protección de Investigación en Humanos

Proceso de Acreditación



Colombian Quality
Award 1999

Colombian Quality in Health
Award – Gold Category

First and Only

Colombian Quality in
Management Award
2005-2006

EL HOSPITAL CON ALMA
Pablo Tobón Uribe

ISO 9001 icontec internacional

ISO 14001 icontec internacional

OHSAS 18001 icontec internacional

efr®

Certificaciones

Premio Colombiano a la Calidad de la Gestión
Versión 1999
Versión 2006

Premio Calidad en Salud Colombia
Categoría Oro
2008

Premios de calidad

Excelencia
ICONTEC
ACREDITACIÓN EN SALUD
INSTITUCIÓN ACREDITADA CON EXCELENCIA

Acreditación en salud con excelencia

Reconocimiento en investigación e innovación 2012

¿Cómo asumimos las distinciones?

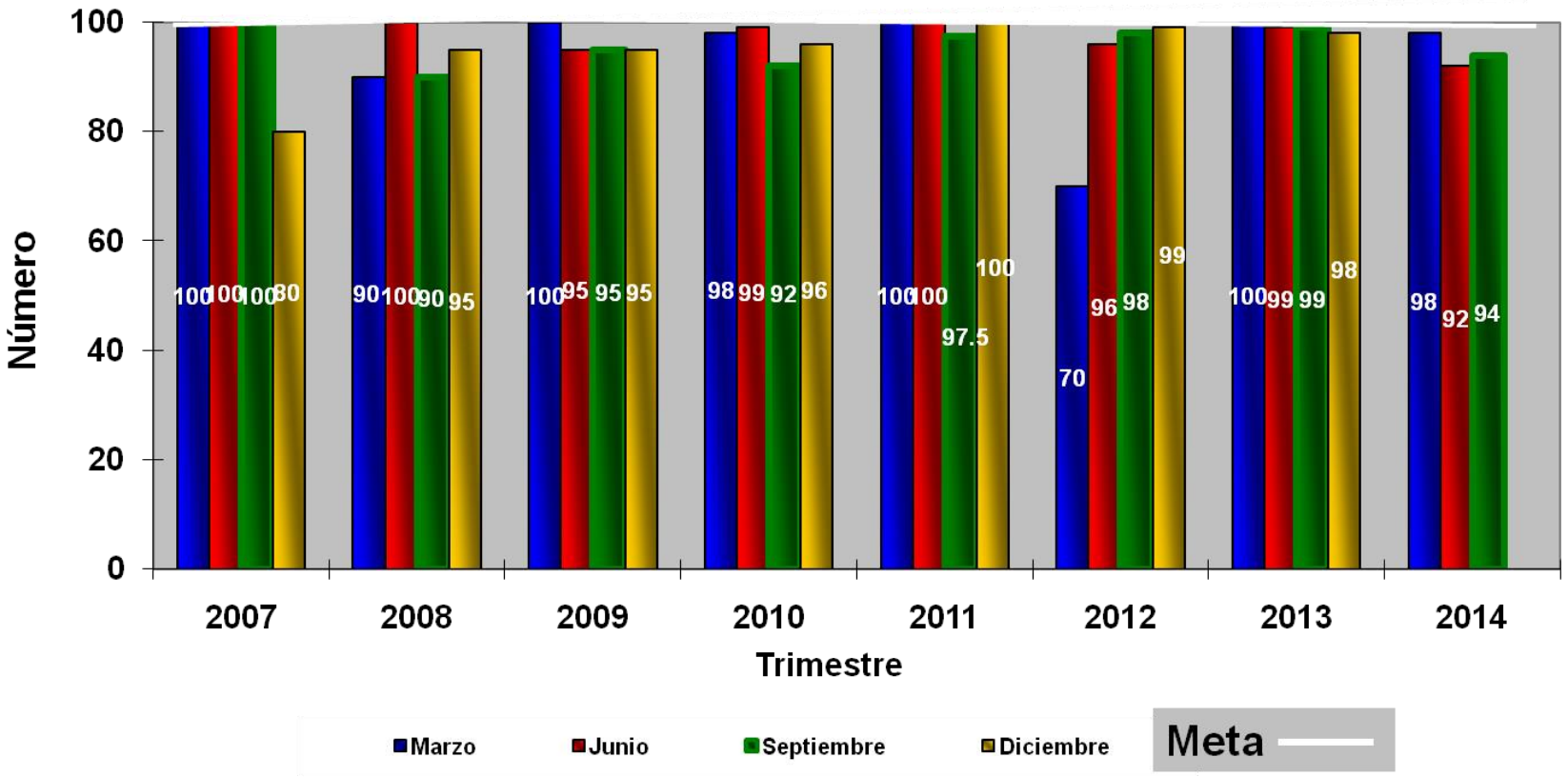
Estímulos del pasado

Responsabilidades en el presente

Retos para el futuro

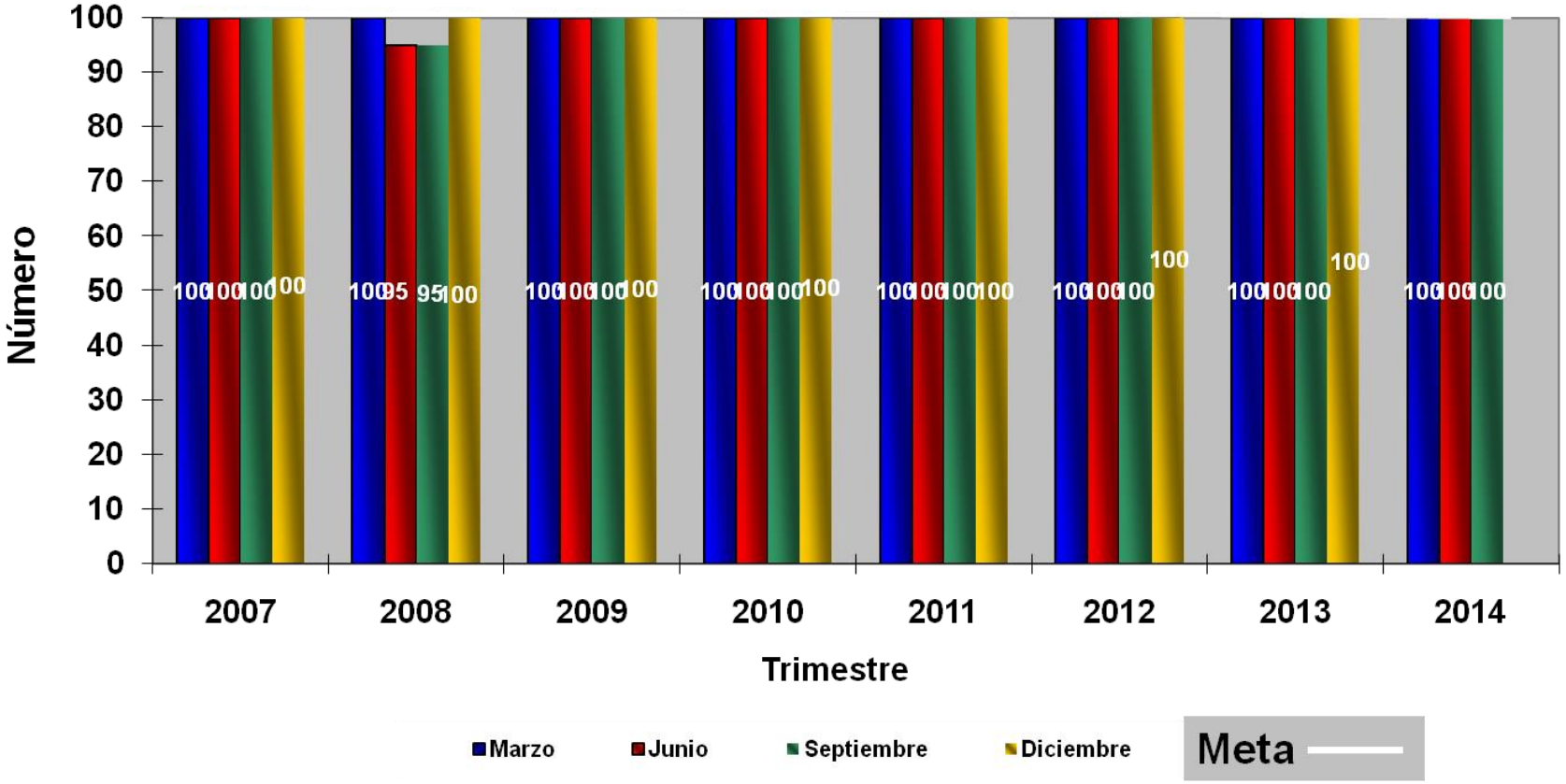
CON ALMA
ón Uribe

Cumplimiento con el adecuado diligenciamiento del consentimiento informado
Meta: 100%



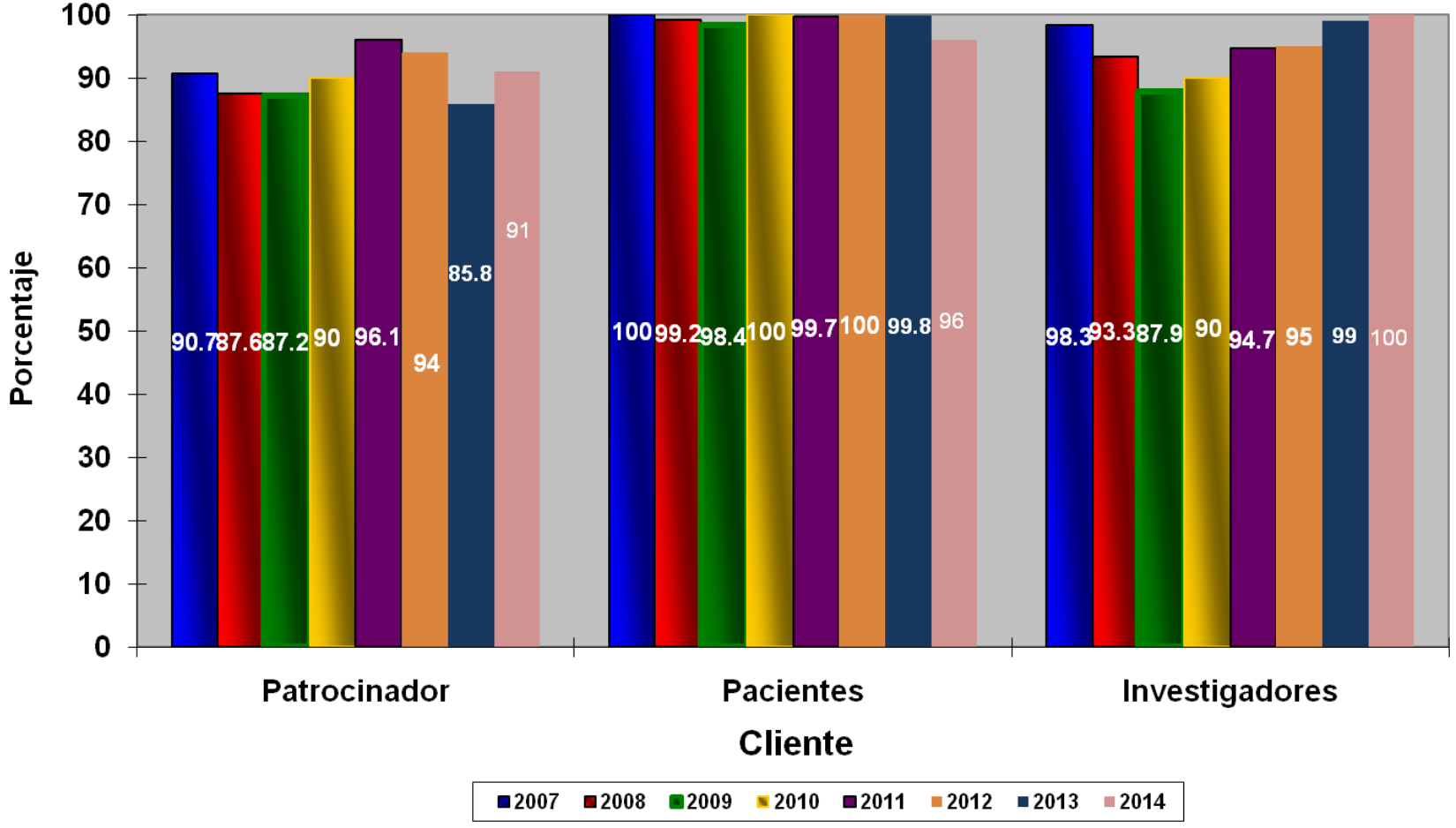
EL HOSPITAL CON ALMA
Pablo Tobón Uribe

Cumplimiento con el reporte oportuno de Eventos Adversos Serios
Meta: 100%



EL HOSPITAL CON ALMA
Pablo Tobón Uribe

Satisfacción con el servicio



EL HOSPITAL CON ALMA
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Software Fund@net

Agenda

1. Direccionamiento estratégico
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4. Ética

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Factibilidades

- Revisión de bases de datos
- Tiempo de respuesta
- Pago por la actividad
- Amenaza: contratación aseguradores

Factibilidades

- **Por el investigador →**

  optimista vs conservador

- **Estudios competitivos**
- **Tiempo de factibilidad vs inicio**

Often the most difficult task in a clinical trial involves obtaining sufficient study participants within a reasonable time. Time is a critical factor for both scientific and logistical reasons. From a scientific viewpoint, there is an optimal window of time within which a clinical trial can and should be completed. Changes in medical practice, including introduction of new treatment options, may make the trial outdated before it is completed.

L.M. Friedman et al. Fundamentals of Clinical Trials

Research

Open Access

What influences recruitment to randomised controlled trials? A review of trials funded by two UK funding agencies

Alison M McDonald*[1], Rosemary C Knight[2], Marion K Campbell[1], Vikki A Entwistle[1], Adrian M Grant[1], Jonathan A Cook[1], Diana R Elbourne[2], David Francis[3], Jo Garcia[2], Ian Roberts[2] and Claire Snowdon[2]

Address: [1]Health Services Research Unit, University of Aberdeen, Polwarth Building, Foresterhill, Aberdeen, UK, [2]Medical Statistics Unit, London School of Hygiene and Tropical Medicine, Keppel Street, London, UK and [3]Centre for Research and Innovation Management, Brighton

Email: Alison M McDonald* - a.mcdonald@abdn.ac.uk; Rosemary C Knight - Rosemary.Knight@lshtm.ac.uk; Marion K Campbell - m.k.campbell@abdn.ac.uk; Vikki A Entwistle - V.A.Entwistle@dundee.ac.uk; Adrian M Grant - a.grant@abdn.ac.uk; Jonathan A Cook - j.a.cook@abdn.ac.uk; Diana R Elbourne - diana.elbourne@lshtm.ac.uk; David Francis - d.l.francis@brighton.ac.uk; Jo Garcia - j.garcia@ioe.ac.uk; Ian Roberts - Ian.Roberts@lshtm.ac.uk; Claire Snowdon - cms1000@cam.ac.uk

* Corresponding author

Published: 07 April 2006

Trials 2006, **7**:9 doi:10.1186/1745-6215-7-9

Received: 20 December 2005
Accepted: 07 April 2006

This article is available from: http://www.trialsjournal.com/content/7/1/9

Trials 2006;7:9

Table 3: Recruitment in trials

	N	n (%)
Recruited successfully	122	
Yes		38 (31.1)
No		84 (68.9)
Was recruitment target revised	*122*	
Yes		42 (34.4)
No		76 (62.3)
Missing		4 (3.3)
Final recruitment figure		
Original target:	122	
≥ 100%		38 (31.1)
≥ 80% but < 100%		29 (23.8)
< 80%		55 (45.1)
Revised target:	42	
≥ 100%		19 (45.2)
≥ 80% but < 100%		15 (35.7)
< 80%		8 (19.1)

Trials 2006;7:9

Reclutamiento

¿Porqué los pacientes elegibles participan en los estudios clínicos?

CLINICAL TRIALS ARTICLE

Clinical Trials 2006; 3: 431–442

Reasons for participation and non-participation in a randomized controlled trial: postal questionnaire surveys of women eligible for TOMBOLA (Trial Of Management of Borderline and Other Low-grade Abnormal smears)

L Sharp[a], SC Cotton[b], L Alexander[c], E Williams[d], NM Gray[b], JM Reid[b], on behalf of the TOMBOLA group

Background Better understanding of motivators for, and barriers to, participation in randomized controlled trials (RCTs) in different study populations and settings has the potential to improve participation of historically under-represented groups (eg, women) in future trials.

Purpose To investigate reasons why women agreed, or declined, to participate in a RCT.

Methods In two postal questionnaire-based studies, we investigated women's reasons for participation or non-participation in TOMBOLA, a RCT comparing management policies for low-grade cervical abnormalities. Four-hundred and ninety-two TOMBOLA participants (response rate 56%) completed questionnaires on reasons for participation. One-hundred and thiry-seven women (38%) who declined TOMBOLA participation completed questionnaires on reasons for this.

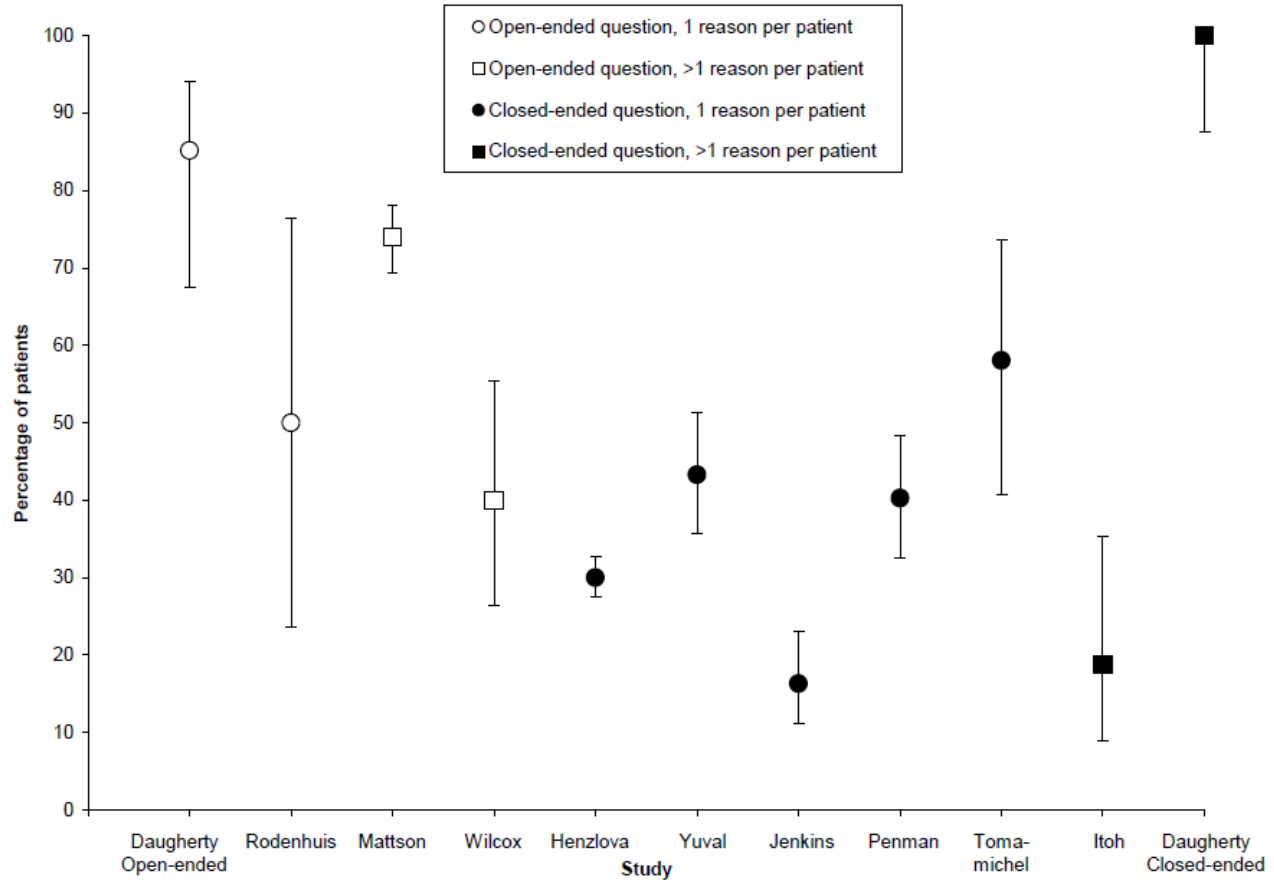
Results Eighty percent of women reported that one of their reasons for attending their TOMBOLA recruitment appointment was worries about their smear result. Ninety-four percent participated in the RCT because it was a worthwhile contribution to the cervical screening programme and other women; for 70% this was the most important reason. These proportions did not vary by socio-demographic factors. Thirty-two percent thought participation would result in better care. The most common reason for non-participation was preference for follow-up from the woman's GP. Logistical issues (eg, inconvenient appointments, travel time, arranging time off work or child-care) were commonly cited. Fourteen percent were too frightened to participate; this was unrelated to the grade of the recruitment smear.

Limitations Response rates were not high, but there was little evidence of response bias. Structured questionnaires were used.

Conclusions Future research should address how best to deliver information to ensure different social groups appreciate potential benefits of RCT participation and provide reassurance regarding fears about participation. Simple strategies (eg, appealing to the altruism of potential participants or offering flexible recruitment clinic locations and times) might enhance RCT recruitment rates. This in turn would ensure best use of research resources thus bringing the greatest benefits to participants and the population. *Clinical Trials* 2006; 3: 431–442. www.sagepub.co.uk

Clinical Trials 2006;3:431-442

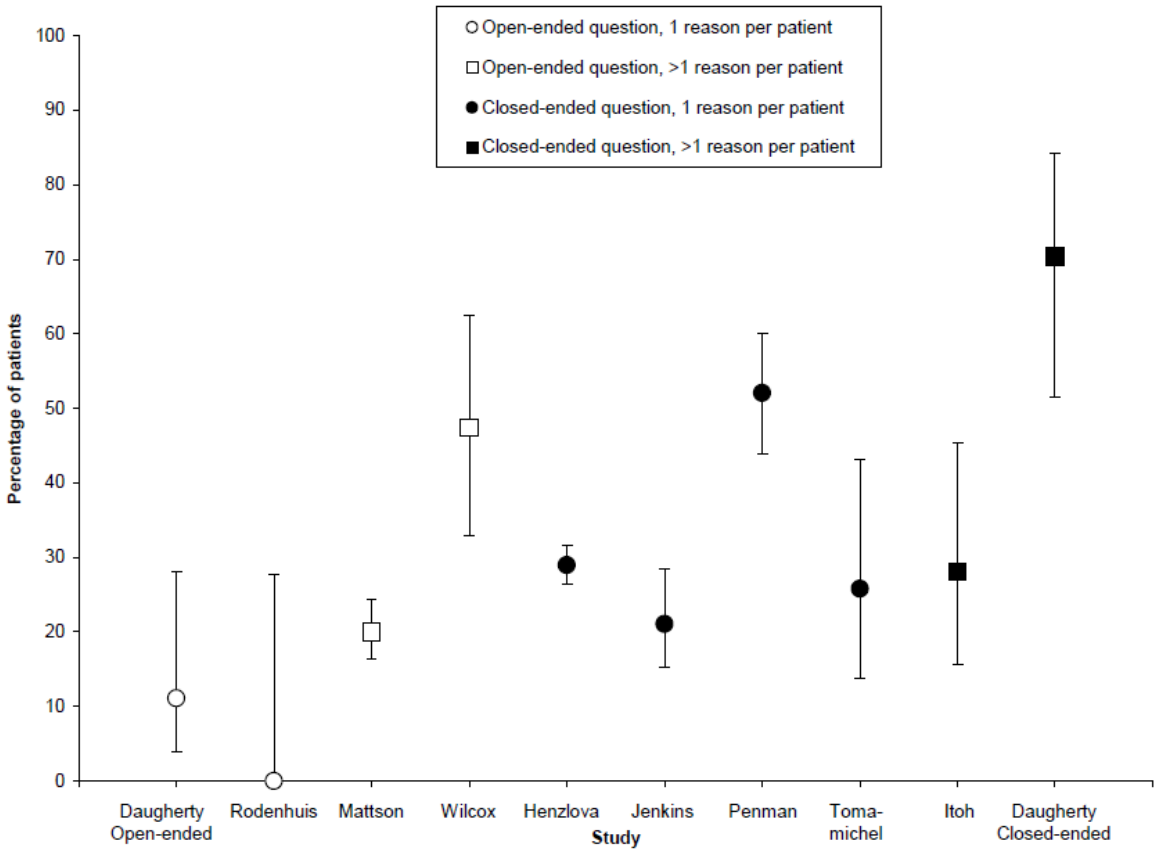
Figure 1. Potential Health Benefit as a Reason for Participation



Error bars represent 95% confidence intervals using the Wilson score method.(18)

ECRI Evidence Report. April 2002, Issue 74

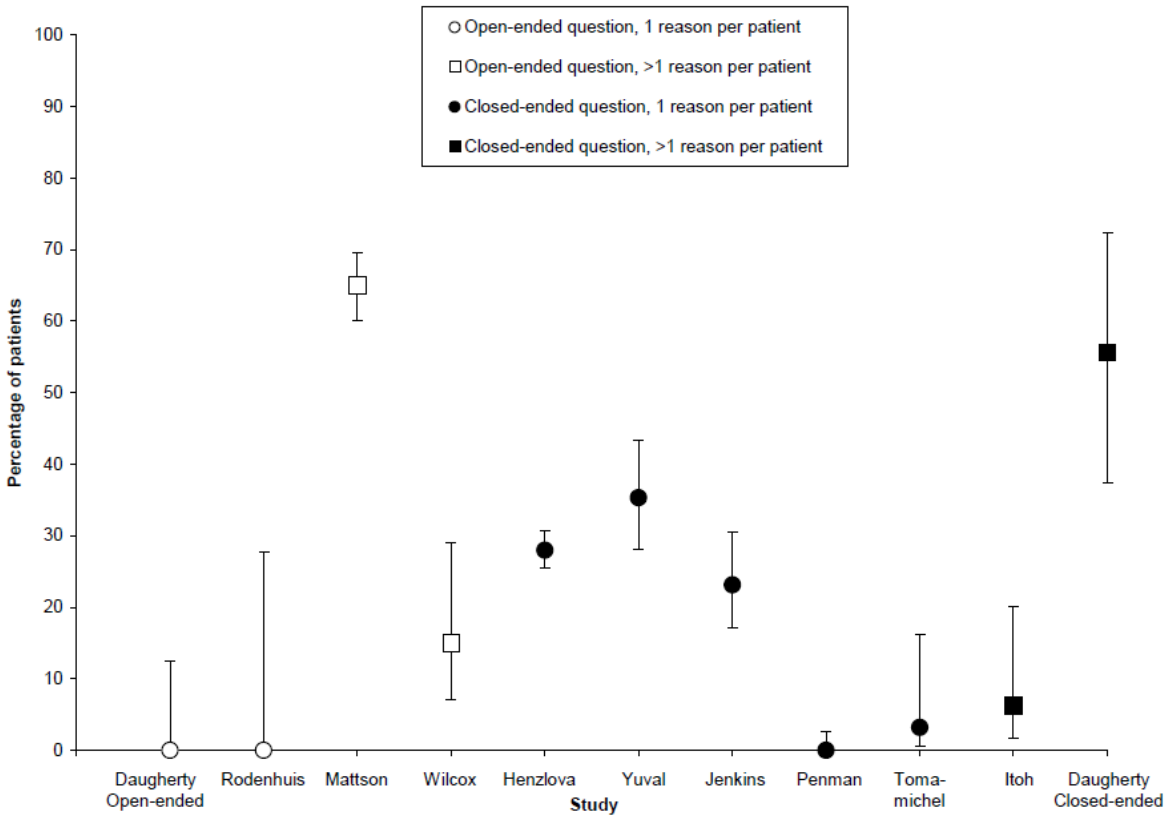
Figure 2. Physician Influence as a Reason for Participation



Error bars represent 95% confidence intervals for proportions using the Wilson score method.(18)

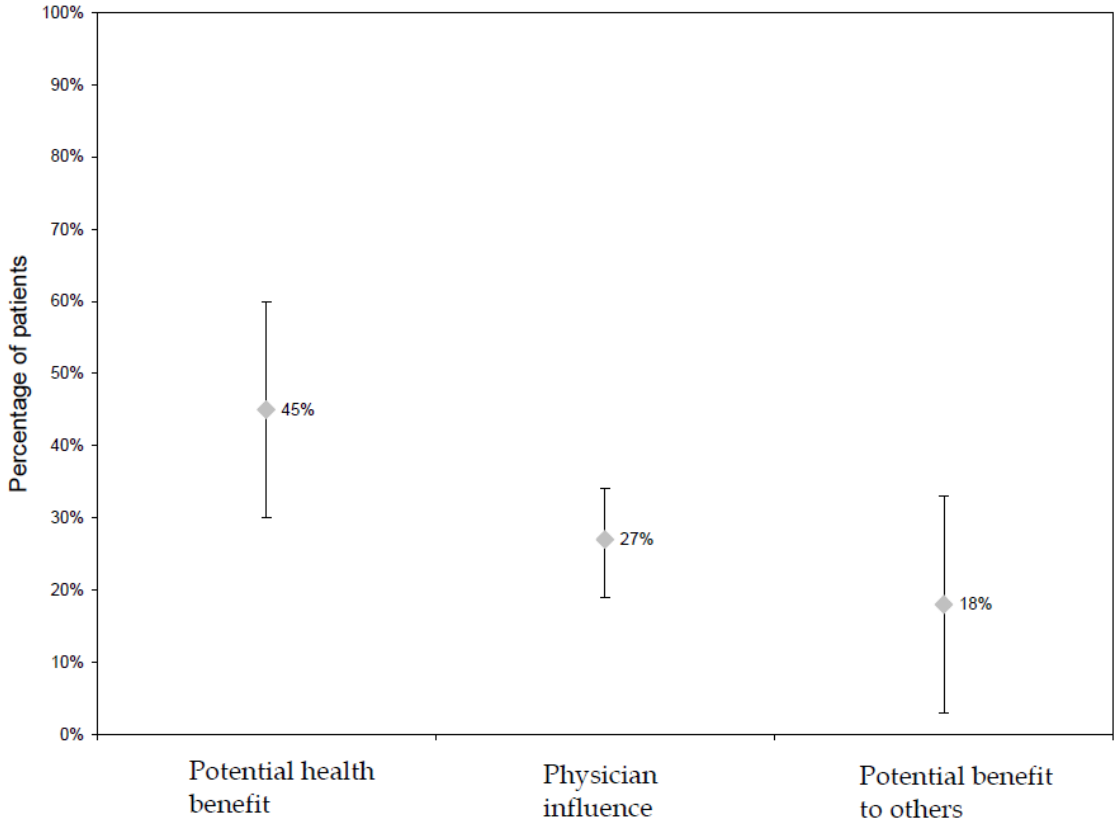
ECRI Evidence Report. April 2002, Issue 74

Figure 3. Potential Benefit to Others as a Reason for Participation



Error bars represent 95% confidence intervals for proportions using the Wilson score method.(18)

Figure 4. Results of Random-Effects Calculations: Reasons for Participation



Error bars represent 95% confidence intervals.

ECRI Evidence Report. April 2002, Issue 74

Reclutamiento

¿Porqué los pacientes potencialmente elegibles no participan en los estudios clínicos?

A systematic review of reasons for nonentry of eligible patients into surgical randomized controlled trials

Ned S. Abraham, MBBS (Hons), MM (Syd), FRACS, FRCS (Engl),[a,b] Jane M. Young, MBBS, MPH, PhD, FAFPHM,[b,c] *and* Michael J. Solomon, MBBCh (Hons), MSc (ClinEpid), FRACS,[b,c] *Coffs Harbour and Sydney, Australia*

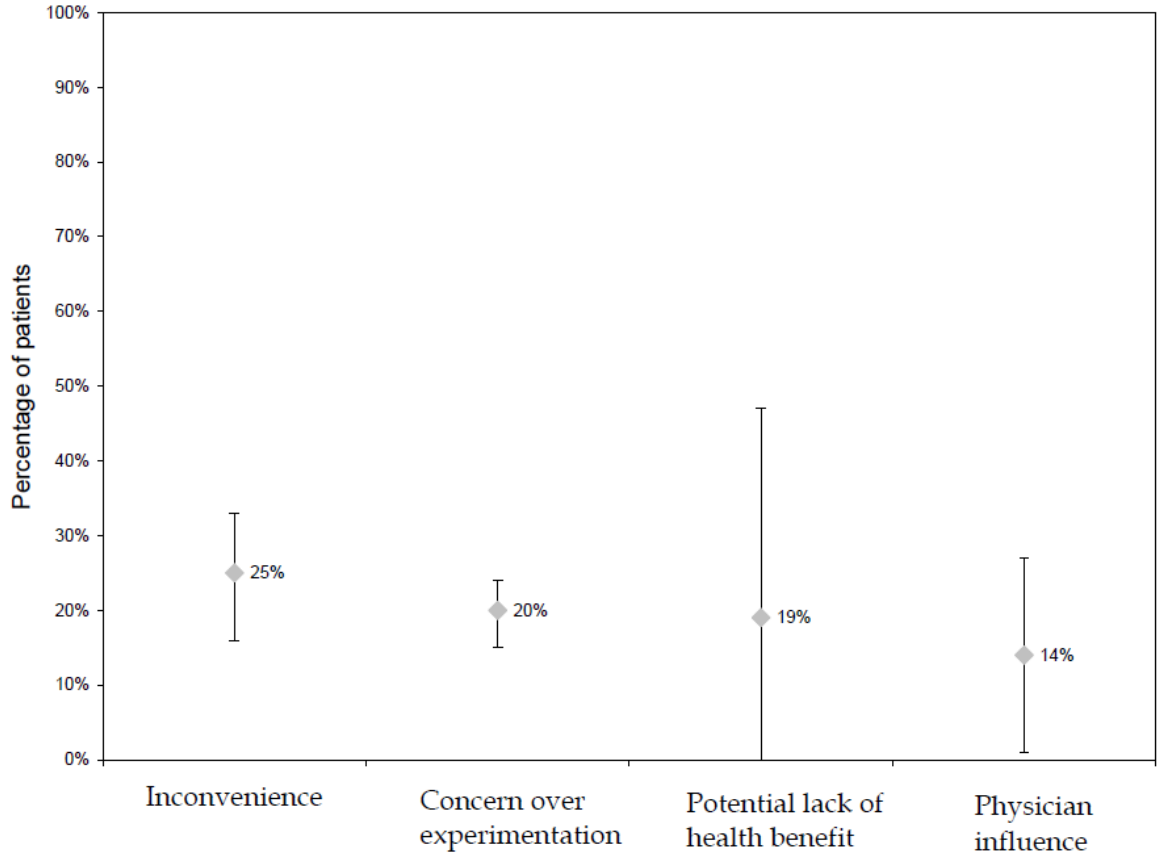
Barriers to participation in clinical trials of cancer: a meta-analysis and systematic review of patient-reported factors

Edward J Mills, Dugald Seely, Beth Rachlis, Lauren Griffith, Ping Wu, Kumanan Wilson, Peter Ellis, James R Wright

Why patients don't take part in cancer clinical trials: an overview of the literature

K. COX, PROFESSSOR, PHD, BSC, RN, *Faculty of Medicine and Health Sciences, School of Nursing, University of Nottingham, Nottingham &* J. MCGARRY MMEDSCI, PGDIP (MEDICAL ETHICS), BA(HONS), RGN, RMN, RESEARCH ASSISTANT, *Faculty of Medicine and Health Sciences, School of Nursing, Medical School Room B50, University of Nottingham, Nottingham*

Figure 6. Results of Random-Effects Calculations: Reasons Against Participation



ECRI Evidence Report. April 2002, Issue 74

Reclutamiento

¿Cuáles estrategias de reclutamiento son útiles para los ensayos clínicos?

Recruitment for Controlled Clinical Trials: Literature Summary and Annotated Bibliography

Laura C. Lovato, MS, Kristin Hill, BA, Stephanie Hertert, MEd, Donald B. Hunninghake, MD, and Jeffrey L. Probstfield, MD

Fred Hutchinson Cancer Research Center, Public Health Sciences, Seattle, Washington (L.C.L., K.H., J.L.P.); Center for Health Research, Kaiser Foundation Hospital, (S. H.); Department of Medicine and Pharmacology, University of Minnesota, Minneapolis, Minnesota (D.B.H.); and Departments of Medicine and Epidemiology, University of Washington Health Sciences Center, Seattle, Washington (J.L.P.)

Control Clin Trial 1997;18:328-357

Reclutamiento

Registros o bases de datos: acceso restringido por regulación

1. **HIPAA**
2. **Ley 1581/2013 Habeas Data**

L.M. Friedman et al. Fundamentals of Clinical Trials

Strategies to improve recruitment to randomised controlled trials (Review)

Treweek S, Mitchell E, Pitkethly M, Cook J, Kjeldstrøm M, Johansen M, Taskila TK, Sullivan F, Wilson S, Jackson C, Jones R, Lockhart P

THE COCHRANE COLLABORATION®

Treweek S, Mitchell E, Pitkethly M, Cook J, Kjeldstrøm M, Johansen M, Taskila TK, Sullivan F, Wilson S, Jackson C, Jones R, Lockhart P. Strategies to improve recruitment to randomised controlled trials. *Cochrane Database of Systematic Reviews* 2010, Issue 4. Art. No.: MR000013. DOI: 10.1002/14651858.MR000013.pub5.

Main results

We identified 45 eligible trials (18 new to this update) with more than 41,239 participants. There were 40 studies involving interventions aimed directly at trial participants, while five evaluated interventions aimed at people recruiting participants. All studies were in health care.

Some interventions were effective in increasing recruitment: telephone reminders to non-respondents (odds ratio (OR) 1.95, 95% CI 1.04 to 3.66; two trials, 1058 participants), use of opt-out, rather than opt-in, procedures for contacting potential trial participants (RR 1.39, 95% CI 1.06 to 1.84; one study, 152 participants) and open designs where participants know which treatment they are receiving in the trial (RR 1.22, 95% CI 1.09 to 1.36; two studies, 4833 participants). However, some of these strategies have disadvantages, which may limit their widespread use. For example, opt-out procedures are controversial and open designs are by definition unblinded. The effects of many other recruitment strategies are unclear; examples include the use of video to provide trial information to potential participants and modifying the training of recruiters. Many studies looked at recruitment to hypothetical trials and it is unclear how applicable these results are to real trials.

Authors' conclusions

There are promising strategies for increasing recruitment to trials: telephone reminders; requiring potential participants to opt-out of being contacted by the trial team regarding taking part in a trial, rather than them having to opt-in, and open designs. Some strategies (e.g. open trial designs) need to be considered carefully before use because they also have disadvantages. For example, opt-out procedures are controversial and open designs are by definition unblinded.

Treweek S, Mitchell E, Pitkethly M, Cook J, Kjeldstrøm M, Johansen M, Taskila TK, Sullivan F, Wilson S, Jackson C, Jones R, Lockhart P. Strategies to improve recruitment to randomised controlled trials. *Cochrane Database of Systematic Reviews* 2010, Issue 4. Art. No.: MR000013. DOI: 10.1002/14651858.MR000013.pub5.

Factors that Influence the Recruitment of Patients to Phase III Studies in Oncology

The Perspective of the Clinical Research Associate

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Peter M. Ellis, M.D., Ph.D.[1,2]
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BACKGROUND. The multiple determinants of a patient's decision to enter into a clinical trial have been explored largely from the perspectives of patients and their physicians. Little research has involved clinical research associates (CRAs) formally, despite their central role in the process of recruitment. The current study was initiated to explore the factors that influence the decision of patients with cancer regarding clinical trial entry, specifically from the perspective of the CRA.
METHODS. Two focus groups of CRAs from the Hamilton Regional Cancer Center were organized. A skilled facilitator guided both groups through *exploratory* and subsequent *confirmatory* phases of discussions, which were audiotaped for review and coding using a process of consensus employing intercoder triangulation.
RESULTS. The two groups identified a number of factors that they believed influenced the recruitment process. Numerous physician and patient factors were reaffirmed, such as the impression of the scientific merit of a study or the sense of personal benefit, respectively. More uniquely, CRAs identified information transfer within the informed consent process as a major aspect of their specialized role. It was believed that full disclosure of information, in terms of both the content and the techniques and styles of delivery, was an important predictor of recruitment success. The groups quickly reached consensus on which factors they believed were the most important overall with respect to influencing study recruitment.
CONCLUSIONS. CRAs appear to have a unique role in the process of recruiting patients to active clinical trials. They believe that they have an important influence

Table 5: Most commonly reported strategies to improve recruitment (N = 122)

STRATEGY	No. trials
Newsletters/mail shots/flyers (to clinical staff and/or patients)	26
Regular visits/phone calls to wards/sites/practices	15
Posters/information leaflets in clinics/wards/notes	13
Inclusion criteria changed/protocol amended	12
Presentations to appropriate groups eg at consultant meetings/community based physiotherapists etc	10
Resource manual for site staff/trained staff in disease area/procedures being investigated/role play exercises/ study day/workshops for recruiters	10
Advertisement/articles in newspapers/journals; radio interviews	8
Presentations at national/international meetings	6
Employed extra staff	6
Investigators'/recruiting staff meetings	5
Training/information videos	4
Incentives for recruiters eg prize draw, chocolates etc	4
Trial material revised/simplified/customised for specific sites	4
Visits to centres by PIs/senior members of study group	3
Repeated contact by phone/letter to individuals/sites	3
Increased/changed time points when information provided to potential participants	3
Supportive statements from opinion leaders	3

Trials 2006;7:9

Research article

Open Access

Increasing recruitment to randomised trials: a review of randomised controlled trials

Judith M Watson* and David J Torgerson

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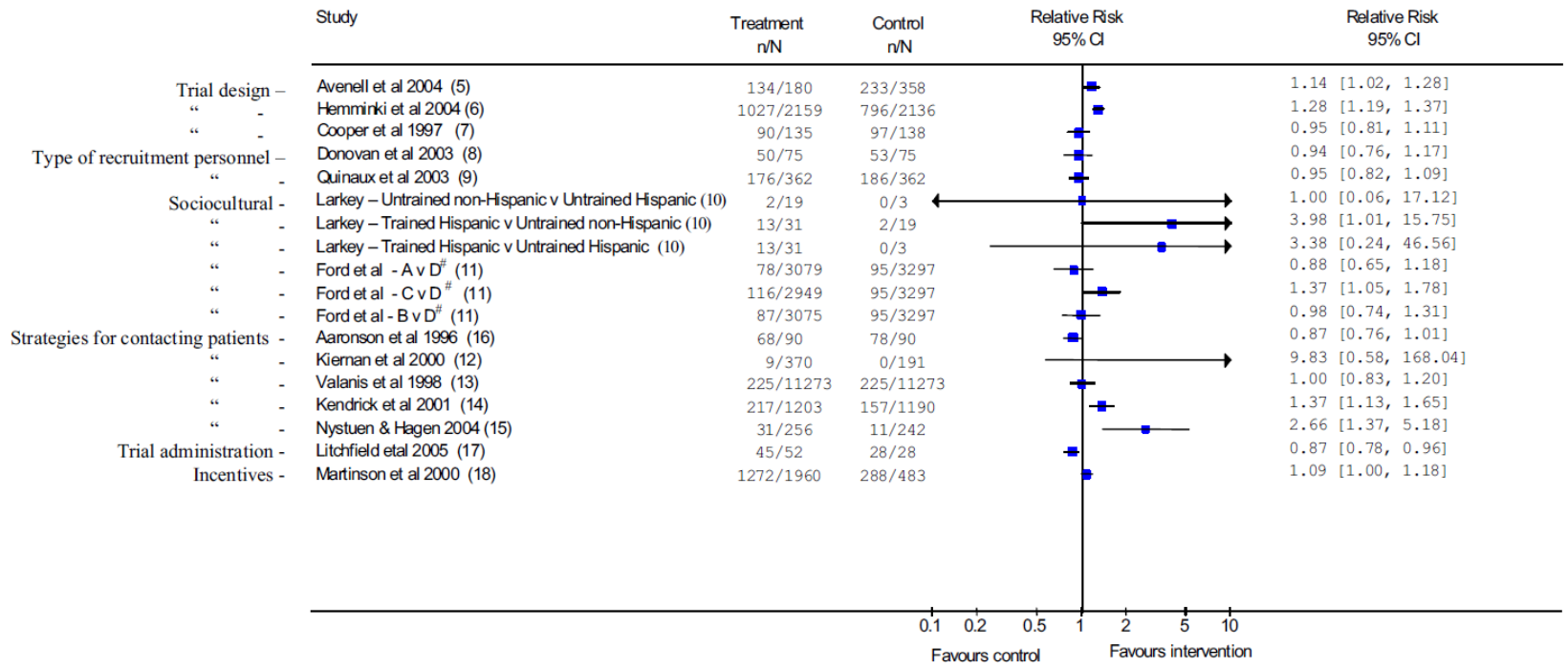
BMC Medical Research Methodology 2006;6:34



Ford – Recruitment process C was more intensive than B, which was more intensive than A. Recruitment process D = control and included the trial's standard recruitment procedures.

BMC Medical Research Methodology 2006;6:34

Strategies for Increasing Recruitment to Randomised Controlled Trials: Systematic Review

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Abstract

Background: Recruitment of participants into randomised controlled trials (RCTs) is critical for successful trial conduct. Although there have been two previous systematic reviews on related topics, the results (which identified specific interventions) were inconclusive and not generalizable. The aim of our study was to evaluate the relative effectiveness of recruitment strategies for participation in RCTs.

Methods and Findings: A systematic review, using the PRISMA guideline for reporting of systematic reviews, that compared methods of recruiting individual study participants into an actual or mock RCT were included. We searched MEDLINE, Embase, The Cochrane Library, and reference lists of relevant studies. From over 16,000 titles or abstracts reviewed, 396 papers were retrieved and 37 studies were included, in which 18,812 of at least 59,354 people approached agreed to participate in a clinical RCT. Recruitment strategies were broadly divided into four groups: novel trial designs (eight studies), recruiter differences (eight studies), incentives (two studies), and provision of trial information (19 studies). Strategies that increased people's awareness of the health problem being studied (e.g., an interactive computer program [relative risk (RR) 1.48, 95% confidence interval (CI) 1.00–2.18], attendance at an education session [RR 1.14, 95% CI 1.01–1.28], addition of a health questionnaire [RR 1.37, 95% CI 1.14–1.66]), or a video about the health condition (RR 1.75, 95% CI 1.11–2.74), and also monetary incentives (RR1.39, 95% CI 1.13–1.64 to RR 1.53, 95% CI 1.28–1.84) improved recruitment. Increasing patients' understanding of the trial process, recruiter differences, and various methods of randomisation and consent design did not show a difference in recruitment. Consent rates were also higher for nonblinded trial design, but differential loss to follow up between groups may jeopardise the study findings. The study's main limitation was the necessity of modifying the search strategy with subsequent search updates because of changes in MEDLINE definitions. The abstracts of previous versions of this systematic review were published in 2002 and 2007.

Conclusion: Recruitment strategies that focus on increasing potential participants' awareness of the health problem being studied, its potential impact on their health, and their engagement in the learning process appeared to increase recruitment to clinical studies. Further trials of recruitment strategies that target engaging participants to increase their awareness of the health problems being studied and the potential impact on their health may confirm this hypothesis.

Please see later in the article for the Editors' Summary.

PloS Med 2010;7:(11)

Reclutamiento

Razones de falla en las metas:

1. Expectativas optimistas
2. Falla de inicio a tiempo
3. Planeación inadecuada
4. Esfuerzo insuficiente

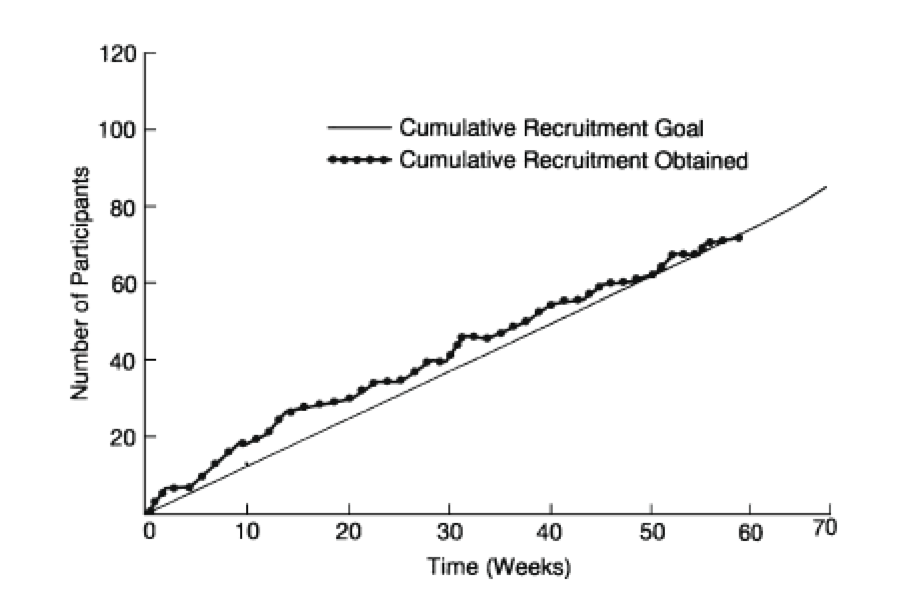
L.M. Friedman et al. Fundamentals of Clinical Trials

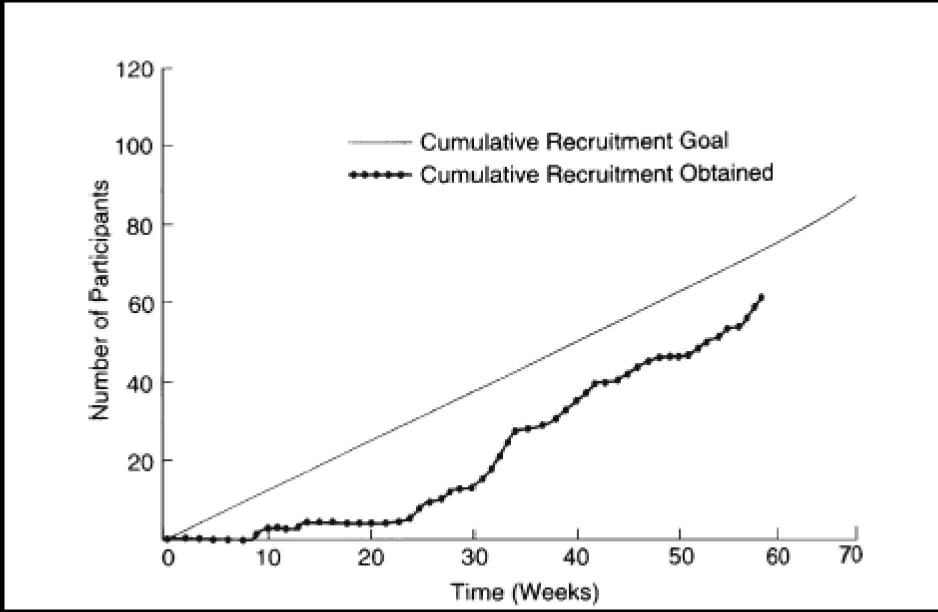
Reclutamiento

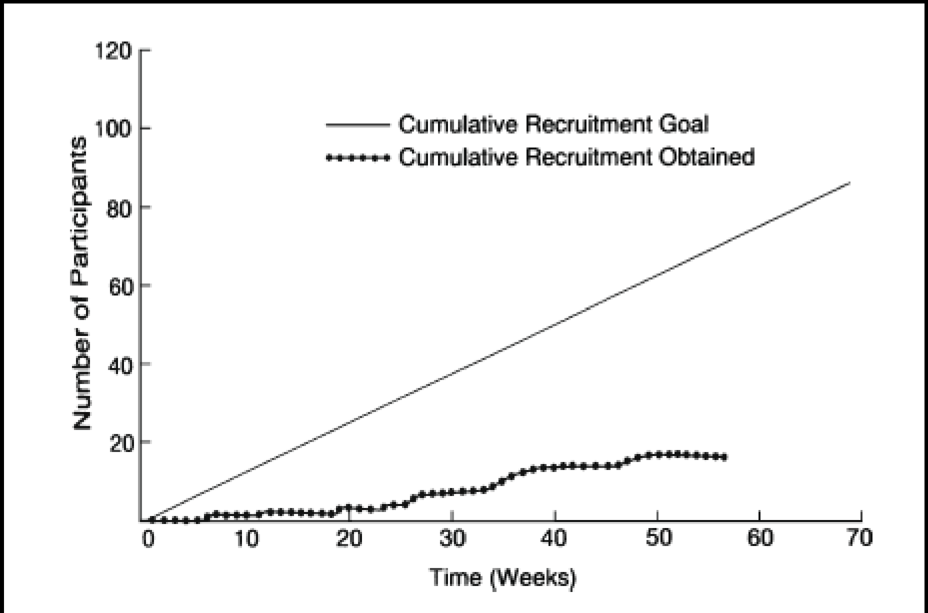
Razones de falla en las metas:

5. Confianza en remisión de colegas
6. Sobreestimación de pacientes potenciales
7. No implementar estrategias de reclutamiento múltiples
8. No tener planes de contingencia

L.M. Friedman et al. Fundamentals of Clinical Trials







L.M. Friedman et al. Fundamentals of Clinical Trials

Mass Mailing and Staff Experience in a Total Recruitment Program for a Clinical Trial: The SHEP Experience

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UMDNJ-Robert Wood Johnson Medical School (N.C., S.K., A.C.W.), University of California at Davis, Davis, California (N.O.B., P.B.); Medical Research Institute of San Francisco, San Francisco, California (G.B.); University of Minnesota (J.L.); John A. Burns School of Medicine (M.H., H.P.); Fred Hutchinson Cancer Research Center (L.C.L., J.L.P.); Cancer Research Center of Hawaii (T.V.); CTB, DECA, NHLBI, Bethesda, Maryland (V.B.), and University of Washington School of Medicine (J.L.P.)

Controlled Clin Trials 1999;20:133-148

Table 1 Clinical Trials Recruitment Strategies and Their Use in SHEP

Recruitment strategies used throughout
Mass mailings
Mass screenings
Media exposure, both paid and unpaid
Hospital and clinic chart review
Recruitment strategies discontinued
Referrals from medical practice
Referrals from blood banks
Referrals from clinical laboratories
Referrals from previous and on-going clinical studies
Recruitment strategies not used
Occupational screenings

Controlled Clin Trials 1999;20:133-148

Table 3 Summary of Screening and Recruitment Activities in SHEP

		Median All Clinics	Range All Clinics	Median % Randomized	Range % Randomized
Total Initial Contact Visits	447,921	19,648	3,928–67,123	1.3	0.4–10.1
Eligible Initial Contact Visits	11,919	696	329–1,313	47.3	20.8–81.6
Randomized	4,736	294	133–599	100.0	100.0

Controlled Clin Trials 1999;20:133-148

Payment to healthcare professionals for patient recruitment to trials: a systematic review

J Bryant, J Powell

Establishing the clinical and cost effectiveness of interventions in healthcare largely depends on good quality randomised controlled trials (RCTs). One element of quality in RCTs is the recruitment of sufficient participants to test a priori hypotheses with statistical confidence and to minimise bias.[1] However, many RCTs fail to meet their recruitment targets.[2]

One strategy to increase recruitment to trials is to pay healthcare professionals to recruit subjects either by providing financial incentives or by reimbursing excess costs incurred. Many pharmaceutical companies provide inducements but this is not common practice in publicly funded research programmes. Such programmes need to have confidence that payments are worthwhile. We did a systematic review, therefore, to synthesise the evidence on the effectiveness of payment to healthcare professionals for patient recruitment to trials.

and the attitudes and characteristics of clinicians in relation to some financial incentive or reimbursement (table).

None set out to test a hypothesis; all relied on finding associations between characteristics of the practice or clinician and patient recruitment. Other methodological limitations included lack of control groups, self selection of respondents, and inadequate data analysis.

One primary care study reported no relation between incentive driven motivation and number of patients recruited[3]; the other primary care study[4] did not report a correlation between financial reimbursement and recruitment rates but concluded from multivariate analysis that patient recruitment by general practitioners may be aided by a range of strategies, including financial incentives. The hospital based study reported that payment to the participating clinics was considered to be of only minor importance for both participation in trials and for recruiting patients.[5]

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BMJ 2005;331:1377–8

BMJ 2005;331:1377-8

What is already known on this topic

Many randomised controlled trials fail to recruit their target number of participants, which has implications for the validity of their findings

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Privately funded research often provides financial incentives to increase patient recruitment, but this is less common in publicly funded research

What this study adds

Evidence on the effectiveness of payment to healthcare professionals for recruiting patients to trials is lacking; funding bodies must consider whether to extrapolate from the evidence of effectiveness of financial incentives in other areas or to undertake new work

BMJ 2005;331:1377-8

Maghera et al. BMC Medical Research Methodology 2014, 14:111
http://www.biomedcentral.com/1471-2288/14/111

BMC Medical Research Methodology

RESEARCH ARTICLE Open Access

You are how you recruit: a cohort and randomized controlled trial of recruitment strategies

Amy Maghera[1], Paul Kahlke[1], Amanda Lau[1], Yiye Zeng[1], Chris Hoskins[4], Tom Corbett[4], Donna Manca[2], Thierry Lacaze-Masmonteil[3], Denise Hemmings[4] and Piush Mandhane[1,5*]

Abstract

Background: Recruitment is a challenge in developing population-representative pregnancy and birth cohorts.

Methods: We developed a collaborative recruitment infrastructure (CRI) to recruit pregnant women for 4 pregnancy cohorts using: faxes from obstetrical offices, in-clinic recruiters, university and funder-driven free-media events, paid-media, and attendance at relevant tradeshows. Recruitment rates and demographic differences were compared between recruitment methods.

Results: We received 5008 referrals over 40 months. Compared to fax, free-media referrals were 13 times more likely to be recruited (OR 13.0, 95% CI 4.2, 40.4: $p < 0.001$) and paid-media referrals were 4 times more likely to be recruited (OR 4.6, 95% CI 2.1, 10.3: $p < 0.001$). Among paid-media advertisements, free-to-read print (e.g. Metro) was the most effective (OR 3.3, 95% CI 2.3, 4.5: $p < 0.05$). Several demographic differences were identified between recruitment methods and against a reference population. Between recruitment methods, media recruits had a similar proportion families with incomes ≥ $40,000 (paid-media: 94.4%; free-media: 93.3%) compared to fax recruits (95.7%), while in-clinic recruits were less likely to have family incomes ≥ $40,000 (88.8%, $p < 0.05$). Maternal recruits from fax and in-clinic were more likely to attend university (Fax: 92.6%, in-clinic 89.8%) versus the reference population (52.0%; $p < 0.05$ for both) and both were less likely to smoke (Fax: 6.8%, in-clinic 4.2%) versus reference (18.6%; $p < 0.05$ for both). However, while fax referrals were more likely to be Caucasian (85.9% versus reference 77.5%; $p < 0.05$), in-clinic referrals were not significantly different (78.2%; $P > 0.05$).

Conclusion: Recruitment methods result in different recruitment rates and participant demographics. A variety of methods are required to recruit a generalizable sample.

Keywords: Recruitment, Birth cohort, Research methods, Sample bias

BMC Medical Research Methodology 2014, 14:111

Odds ratio (OR) of recruiting a pregnant woman by recruitment method* (n = 2685)

	Number of recruits	Odds ratio [95% CI]	p-value
Fax	28% (308/1112)	Reference	
Direct	43% (17/40)	1.93 (0.41 - 9.01)	0.40
In-clinic	31% (399/1291)	1.02 (0.84 - 1.25)	0.81
Media			
Free-media	68.0% (77/114)	12.99 (4.18 - 40.43)	<0.001
Paid-media	72.0% (86/120)	4.63 (2.08 - 10.31)	<0.001
Tradeshows			
No raffle was held	21% (82/398)	0.56 (0.41 - 0.75)	<0.001
A raffle was held	12% (11/92)	0.28 (0.14 - 0.58)	<0.001

Goodness of fit (p-value) = 0.79 (not significant indicating good fit).
*Analysis controlled for recruiting study, gestational age and family

BMC Medical Research Methodology 2014, 14:111

Estrategias de Reclutamiento

- Bases de datos
- HCE
- Canal HPTU-TV
- Contacto con colegas
- Call Center del Hospital
- Avisos en el Hospital
- Boletín En Familia
- Periódico El Colombiano

Reclutamiento Pacientes

Tipo de estrategia	*Fecha de implementación*
1. Avisos en carteleras del Hospital	
2. Aviso en boletín En Familia	
3. Reuniones en grupo primario de especialidades	
4. Contacto con colegas de otras instituciones	
5. Contacto con otras IPS o EPS	
6. Aviso publicitario en prensa pagado	
7. Aviso académico en prensa no pagado	
8. Reunión de grupos de pacientes potenciales para tamizaje, ejemplo de La Quintana	
9. Revisión de bases de datos de pacientes del Hospital	
10. Conversatorios en emisoras de radio	
11. Asistir a las Unidades Intermedias de Salud o Centros de segundo nivel de atención	
12. Comidas con médicos potenciales remisores de pacientes	
13. Pacientes tomados de la consulta médica del investigador principal	
14. Plegable con información de la unidad de investigaciones	
15. Volantes invitando al estudio de investigación y se reparten por las zonas comunes del hospital	
16. Reunión académica con los médicos generales y especialistas de interés.	
17. Información en los club de revistas del hospital	
18. Stand promocional con la unidad de investigaciones	


TIPOS DE DIABETES
DIABETES TIPO I
✓Llamada juvenil o de la infancia, caracterizada por la carencia de la

¿Sufre usted de migraña junto con enfermedad coronaria y está interesado en participar con nosotros en una investigación?

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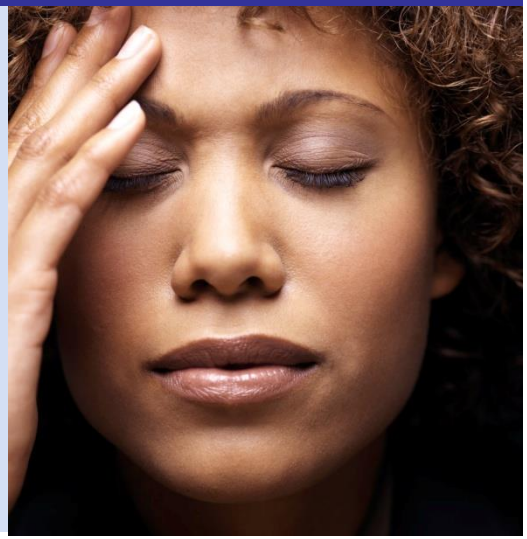

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EL HOSPITAL CON ALMA
Pablo Tobón Uribe

El Colombiano
Medellín, jueves 12 de marzo de 2009

Salud

Editor: Beatriz Arango [beatrizar@elcolombiano.com.co]

NOTICIA [INFORMA / TIEMPO DE LECTURA: 2 MIN.]

MARIO ALBERTO DUQUE CARDOZO
Medellín

Migrañas
entre cabeza y corazón

EL HOSPITAL PABLO Tobón Uribe adelanta una investigación sobre este tipo de cefaleas y su relación con la enfermedad coronaria. La unidad de investigaciones está, además, buscando pacientes que hagan parte del estudio.

Para efectos de este cálculo, supóngase que se reúnen 100 hombres y 100 mujeres en un salón.

Dieciocho de ellas y seis de ellos sufrirán de un determinada cefalea denominada migraña.

Esas son las estadísticas de Estados Unidos, que para el caso, refleja lo común que resulta este padecimiento que puede llegar a ser incapacitante.

La migraña, explica el neurólogo Basilio Vagner del Hospital Pablo Tobón Uribe, no se trata de un simple dolor de cabeza.

"Es más intenso y puede estar asociado con otras patologías, como las enfermedades cardiovascular o cerebrovascular", indica el especialista.

El dolor puede ser de intensidad variable, agrega el neurólogo y afirma que "así como hay unas incapacitantes, hay otras tolerables".

Además, aclara, no es solamente una forma de dolor de cabeza, es un complejo multisintomático que presenta repercusiones en distintos niveles del organismo, dentro de los cuales la cefalea es la representación más importante.

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Pablo Tobón Uribe

El Colombiano
Medellín, jueves 29 de octubre de 2009

Editora: Beatriz Arango [beatrizar@elcolombiano.com.co]

NOTICIA [CONECTA / TIEMPO DE LECTURA: 2 MIN.]

El corazón se cuida desde los dos años de edad

EN EL HOSPITAL Pablo Tobón Uribe adelantan una investigación sobre colesterol en niños entre 6 y 11 años. Se requieren voluntarios.

"Hay que sensibilizar a la ciudadanía que la enfermedad cardiovascular se previene desde que se tienen dos años de vida. El gen corre por familias e incluso puede pasar de abuelos a nietos"

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Pablo Tobón Uribe

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Si Usted, un familiar o un conocido **están interesados en participar** en alguna de nuestras investigaciones, comuníquese con:

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Adelantamos estudios clínicos sobre nuevos tratamientos para pacientes con falla cardiaca, diabetes mellitus, cáncer de seno, artritis, lupus, hipertensión arterial-obesidad, colitis ulcerativa y otras enfermedades.

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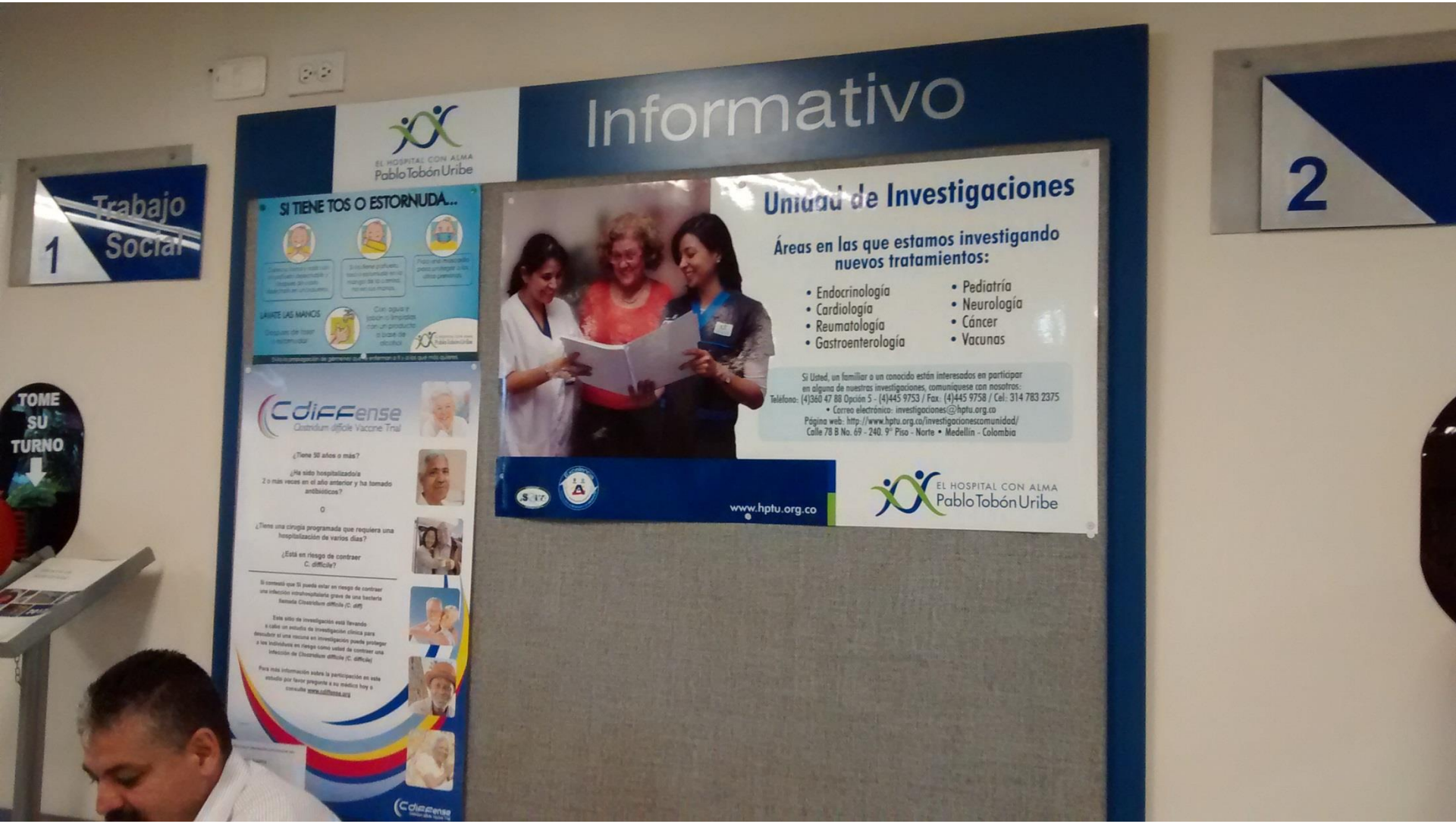

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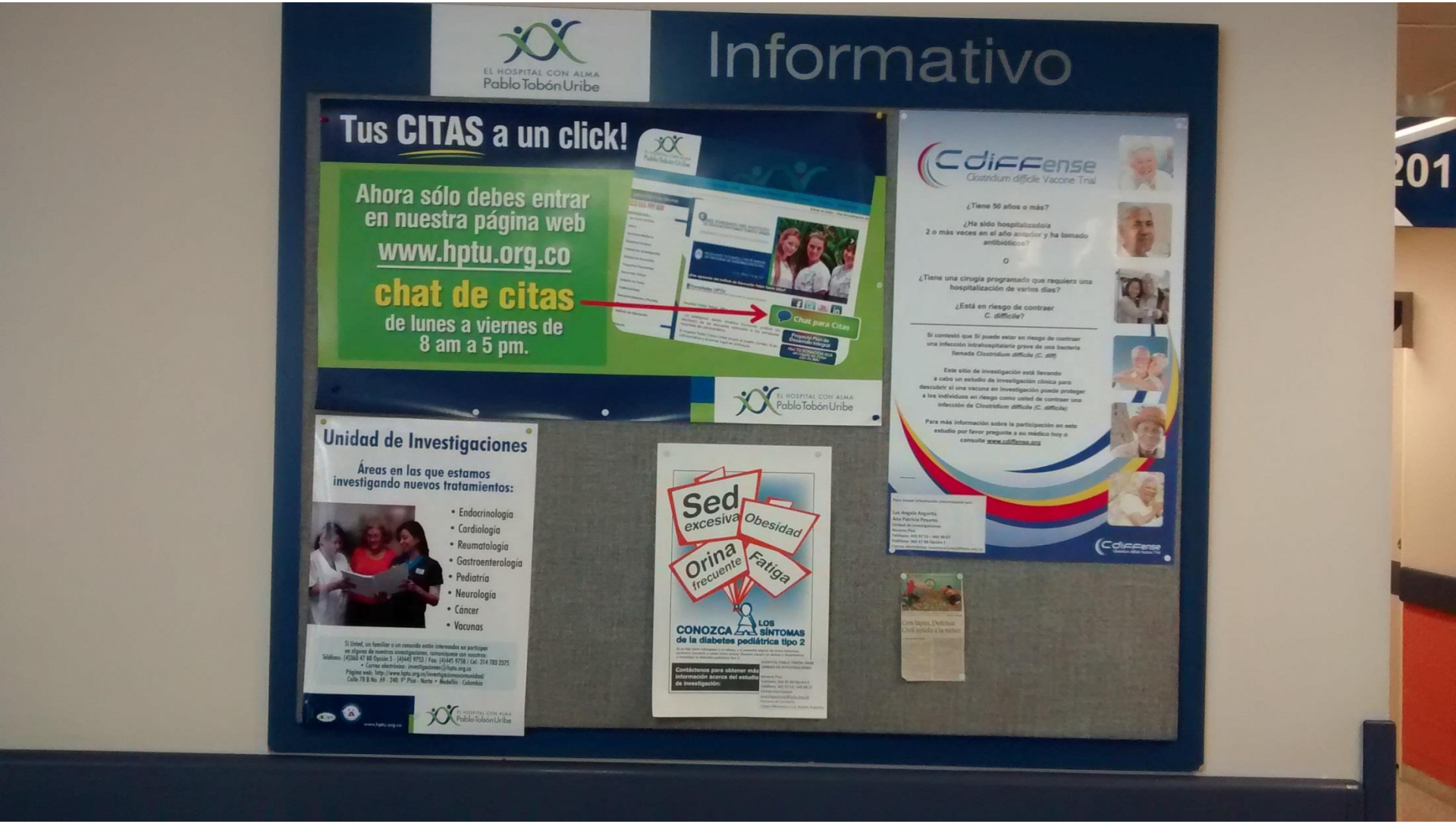

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EL HOSPITAL CON ALMA
Pablo Tobón Uribe

Agenda

1. Direccionamiento estratégico
2. Política de calidad
3. Reclutamiento
4. Ética

OPEN ACCESS

EXTENDED REPORT

A randomised, double-blind, parallel-group study to demonstrate equivalence in efficacy and safety of CT-P13 compared with innovator infliximab when coadministered with methotrexate in patients with active rheumatoid arthritis: the PLANETRA study

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Yoo DH, *et al*. *Ann Rheum Dis* 2013;**72**:1613–1620. doi:10.1136/annrheumdis-2012-203090

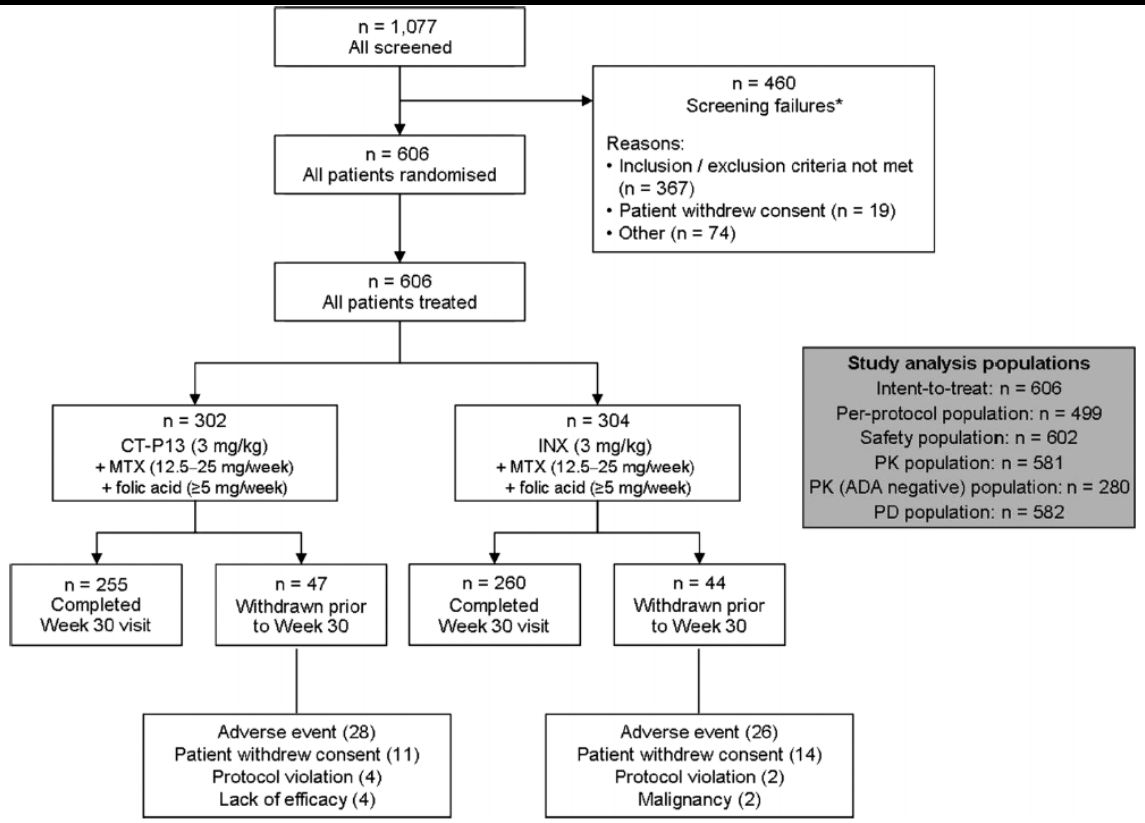

Figure 1 Flowchart of patient disposition. A total of 1077 patients were screened for the study, and 606 eligible patients were randomised into a CT-P13 group (N=302) or an innovator infliximab (INX) group (N=304) to receive 3 mg/kg of CT-P13 or INX, respectively, coadministered with methotrexate (MTX) and folic acid. All 606 randomly assigned patients were included in the intention-to-treat population. A total of 107 out of 606 randomised patients were excluded from the per-protocol population due to the various protocol violations. *Eleven patients from a potentially fraudulent study site were excluded from analyses.

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Stenting and Medical Therapy for Atherosclerotic Renal-Artery Stenosis

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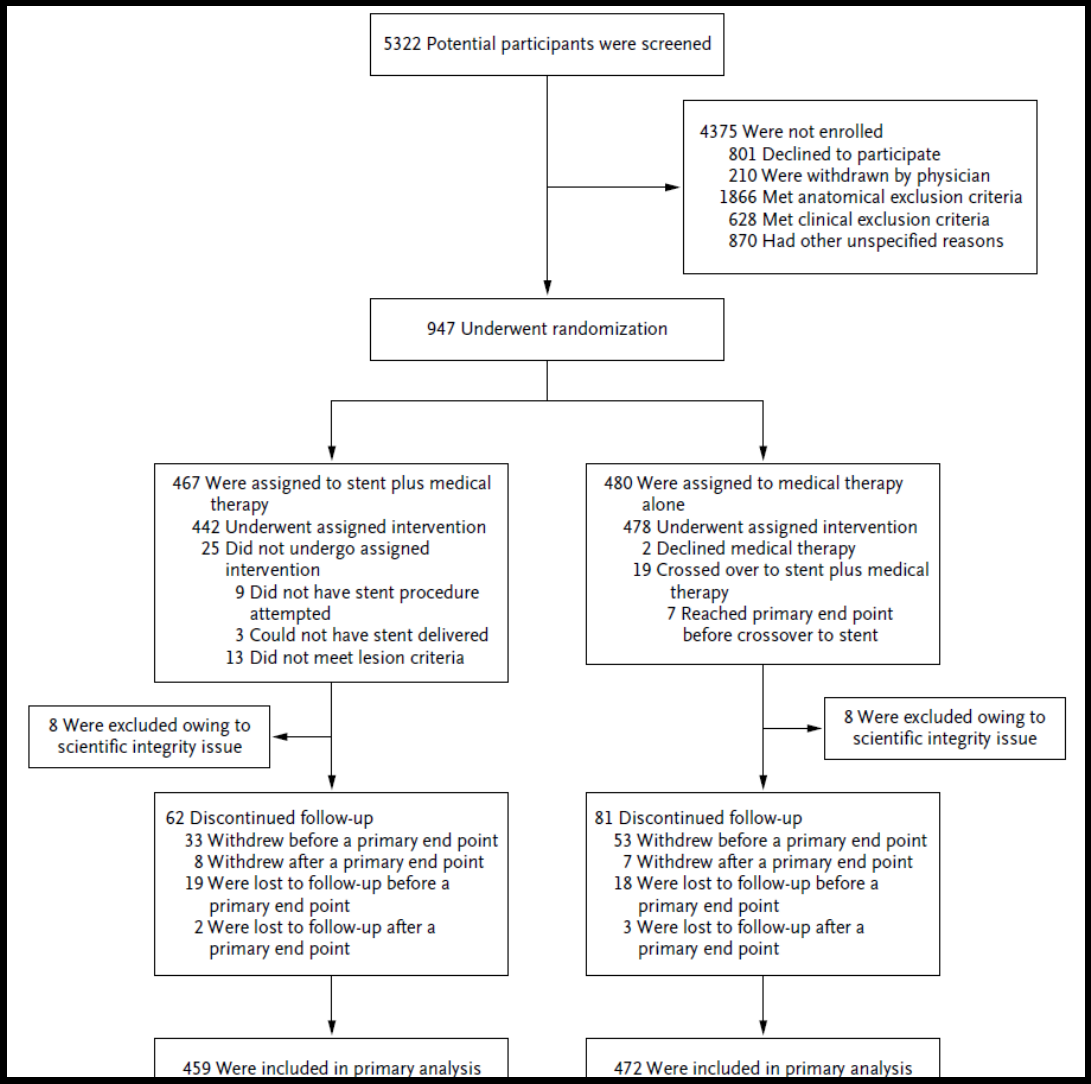
N Engl J Med 2014; 370:13-22



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All the analyses were performed on an intention-to-treat basis. All participants who underwent randomization were included in the intention-to-treat analyses with the exception of the 16 participants (8 in each group) who were enrolled at a single site at which scientific integrity issues were identified; an administrative decision was made to exclude the data from these participants from the intention-to-treat analysis

N Engl J Med 2014; 370:13-22

En conclusión

1. Direccionamiento estratégico
2. Política de calidad
3. Reclutamiento
4. Ética