Sustainable Relationships between Industry Donor and Patient Organization – What Are the Secrets?

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Why I Believe It Can Work

- Because I have worked for 20+ years in the industry, and I have kept genuine friends in the patient community, years after we stopped having a professional relationship…
- Because nothing, nothing matters to decent people in the industry more than making sure patients get the best possible treatment
- Because in today’s environment, industry has not only a moral but a financial obligation to demonstrate that their drugs are used appropriately: in the right way to the patients most likely to benefit from them!

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Why I Know It Can Work

Almirall

Baxter

Bayer HealthCare
Bayer Schering Pharma

biogen idec

Bioness

Coloplast

Ernst & Young
Quality In Everything We Do

genzyme

gsk GlaxoSmithKline

Glycominds

Lilly
Answers That Matter.

LOYENS

Merck Serono

Medtronic

Medtronic Foundation

Novartis Neuroscience

Pfizer

sanofi aventis

TEVA

Because all these companies support EMSP regularly, even though it is not your purpose to help them sell their drugs…

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What It Shouldn't Look Like…

What Do Pharma Companies Want?

- Of course, they want to sell their drugs!
- They want reimbursement for their latest drug
- They want to recruit patients in their trials
- They want to understand patients’ perspective on the disease
- They want to help patients improve the quality of their dialogue with physicians, particularly highly-trained specialists

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Tysabri Was a Watershed!

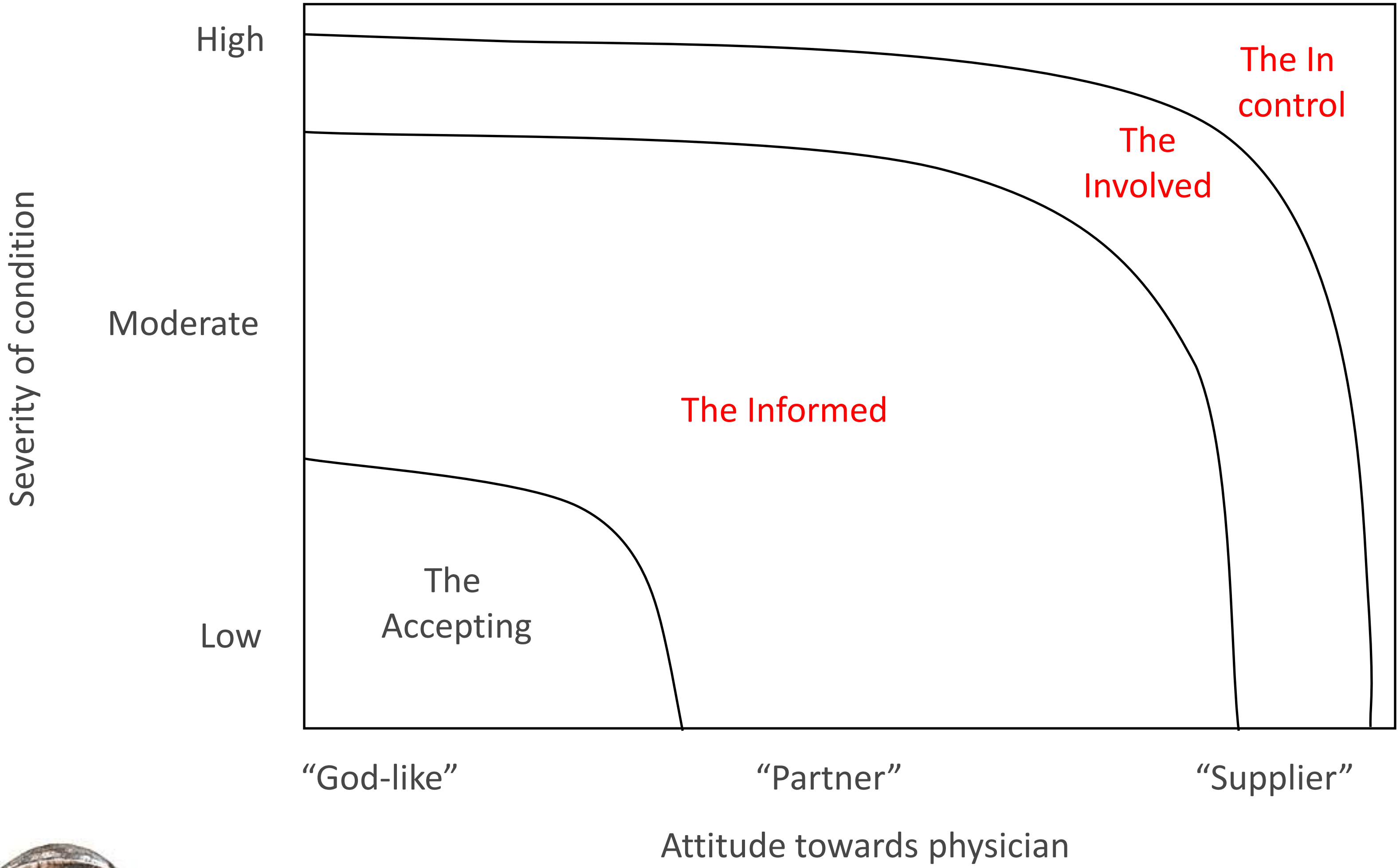
- Natalizumab (Tysabri) is a great drug, but!
- Efficacy was about double that of IFN-ß…
- …but 3 patients contracted PML during clinical trials (about 1 in 1,000) and 2 died!
- FDA or EMA would normally have rejected the drug as presenting an unacceptable risk/benefit ratio
- Patient advocacy groups were decisive in demanding regulatory agencies approve the drug

The Patient Is No Longer Passive...

"I'M SORRY DOCTOR, BUT AGAIN I HAVE TO DISAGREE!"

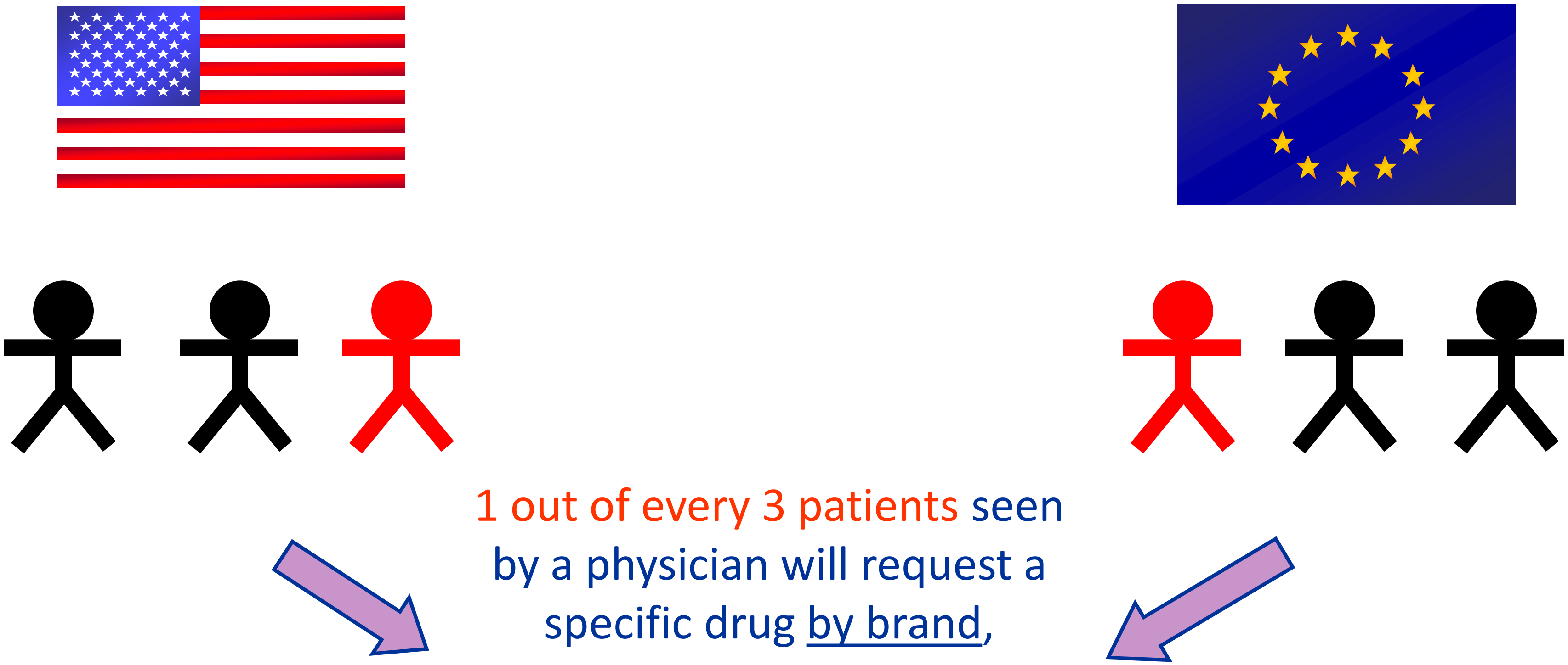
British Medical Journal 1999;319(18 September):762.

Patients Are Getting More Involved



Note: Weighted to population on online chronically ill, if weighted to overall chronically ill population (accepting, 12% ; informed, 59%; involved 22%; in control 7%)
Source: Harris Interactive 10,000 patient survey (Oct-99) and BCG analysis

DTC Advertising Is Clearly Not The Only Source of Patient Information !



1 out of every 3 patients seen by a physician will request a specific drug by brand, in the US and in Europe!

Sept 2003 – Consumer Health Sciences (CHS) : The National Health and Wellness Survey (NHWS), a self-administered survey of 36,450 adult patients in the USA and 17,100 in the UK, France and Germany

Patient Communication in the EU

- Any information directed to patients on Rx drugs is forbidden by EU Directives 92/28/EEC and 2001/83/EC.
- This results in a strange situation where anyone can say anything about a drug in any media… except the company that discovered and sells it!
- The EC has recognized this paradox and has issued Directive proposal 2008/0256 that would allow some direct communication between the pharmaceutical industry and consumers.

Directive Proposal 2008/0256

- The European Commission recognized that it would be in the patients' best interest to receive "high-quality non-promotional information about the benefits and risks of medicinal products" from MA holders.
- The EC makes a distinction between "push" (active, unsolicited) and "pull" communication (passive, at the patient's initiative and discretion): only "pull" communication would be authorized.
- DTC advertising (the ultimate "push" tactic) would remain banned, but e-marketing will probably increase exponentially.

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Non-Promotional Communication

- DTC is forbidden in the EU (Directives 92/28/EEC and 2001/83/EC), and legislative proposals from the EC (Directive proposal 2008/0256) would allow MA holders to disseminate only “high-quality non-promotional information about the benefits and the risks of medicinal products”
- All contacts with patient advocacy groups and individual patients should be handled by Medical Affairs personnel

Reaching a Win/Win/Win Relationship

- Have a candid discussion with your industry counterparts about your and their Short-Term and Long-Term objectives
- Compare and contrast your goals and identify very precisely areas of common interest and programs you can run together
- Delineate also clearly what you are not ready to do for each other, and agree on where your collaboration will stop: you will never endorse their product

Preserving Your Reputation

- Obviously, you cannot under any circumstance compromise on your core values of independence, integrity and transparency
- Know when to say no…
- Diversify your sources of funding so that you never become so dependent on one donor that you cannot risk alienate it.

Starting on the Right Foot

- Arrange for a face-to-face meeting once contact has been initiated
- Present your advocacy mission, followed by clear and transparent objectives relating to your specific program objectives. Discuss how your group operates in terms of industry relationships and begin to understand or re-confirm how the industry donor itself likes to work
- Mutual recognition and respect of each other’s objectives and goals is the critical primary step, before even engaging in discussions on specific support for project or program ideas.

Building a Long-Term Relationship

- Identify areas where you can both benefit from a sustained effort (patient education, improving patient-physician dialogue, helping the innovation process,…)
- Be honest, be direct, don’t avoid difficult discussions
- Behave in a business-like manner: come prepared, keep your commitments, be discrete about your discussions

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Establishing Trust

- Keep and share minutes of your meetings
- Establish written contracts detailing the support you will give each other (financial, personal, other commitments)
- Communicate regularly and don't hesitate to give positive and negative feedback to each other
- Be willing to discuss projects that may be in principle difficult for you

Canine Assistants

Training Great Dogs to Help Special People

Canine Assistants is a non-profit organization, founded in 1991, which trains and provides service dogs for children and adults with physical disabilities or other special needs. In addition to physically assisting those with disabilities, Canine Assistants service dogs are instrumental in removing many of the barriers faced by the disabled in today's society. One recipient made the value of this skill quite clear when asked by a reporter what she liked most about her service dog. Immediately, she responded, "My dog makes my wheelchair disappear."

Our Current Newsletter

* PDF (Adobe Acrobat file) - 268K

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Sky

Pleased in Belize 4

GREENVILLE, S.C. ORCAS ISLAND BERKELEY CHINA SMITHVILLE, TENN. NEW YORK NANTUCKET CHIANTI

Berlin, Boldly

It's *fancy* and (sometimes) *free* in the German metropolis 31

There's Wine in North Carolina— AND you can *drink it*! 52

The MODERNIST side of Tel Aviv 72

SPAHOUND: a ritual purification in Punta Mita 23

Sky Magazine
(in-flight magazine
of Delta Airlines)
April 2006

Now your SkyMiles can bring best friends together.

Delta

Meet best friends Lindsey and Wonder. The friendship you see here goes far beyond that of a girl and her dog. Wonder is a service dog trained by Canine Assistants and, like all our dogs, she knows over 90 commands—from opening doors to summoning help—that can help Lindsey cope with the challenges of everyday life.

And Wonder knows that Lindsey is the most perfect little girl in the whole world, because best friends don't see disabilities.

While Lindsey's life has been changed for the better, we have thousands of other people still waiting. Please help us bring more best friends together by donating your Delta SkyMiles to Canine Assistants at **www.delta.com/skywish**. Visit **www.canineassistants.org** to learn more.

This information is provided as a courtesy to readers of *Sky* magazine by UCB, The Epilepsy Company.

Possible Initiatives

- Establish standing Patient Advisory Board by disease
- Make patient insight a key component of Brand Plan, and "patient metrics" in all Market Research studies
- Involve patients systematically in developing promotional materials (tone, language, images,...) and Market Research questionnaires
- Provide forum for NGOs to share best practices on patient support services, help patient support groups with admin/PR support
- Pilot "total care" solution for severe chronic disease (e.g. Blackberry to patient for online support, disease information, drug compliance, patient diary, physician finding, respite for caregivers? etc...)
- Use response card/opt-in mechanisms on all patient & caregiver communications

Patient-Centric Checklist

- **R & D**
  - At what stage do you identify / involve physician & patient KOLs?
  - How do you uncover unmet needs / by what methods?
  - How do you link with / support advocacy groups?
- **Manufacturing**
  - How / when are market & patient data integrated into forecasts?
  - Do patient / physician needs drive formulations, dosing, delivery systems?
- **Sales**
  - How do you help foster physician / patient dialogue? What education tools have you built?
  - What channels do you use (offline / online)?
- **Marketing**
  - What disease awareness / screening programs do you offer? – measurable impact?
  - What patient access programs? How are they communicated?
  - How do you collaborate with advocacy groups?
  - How do you involve all employees in understanding the patient / caregiver experience of disease?

Illustrative

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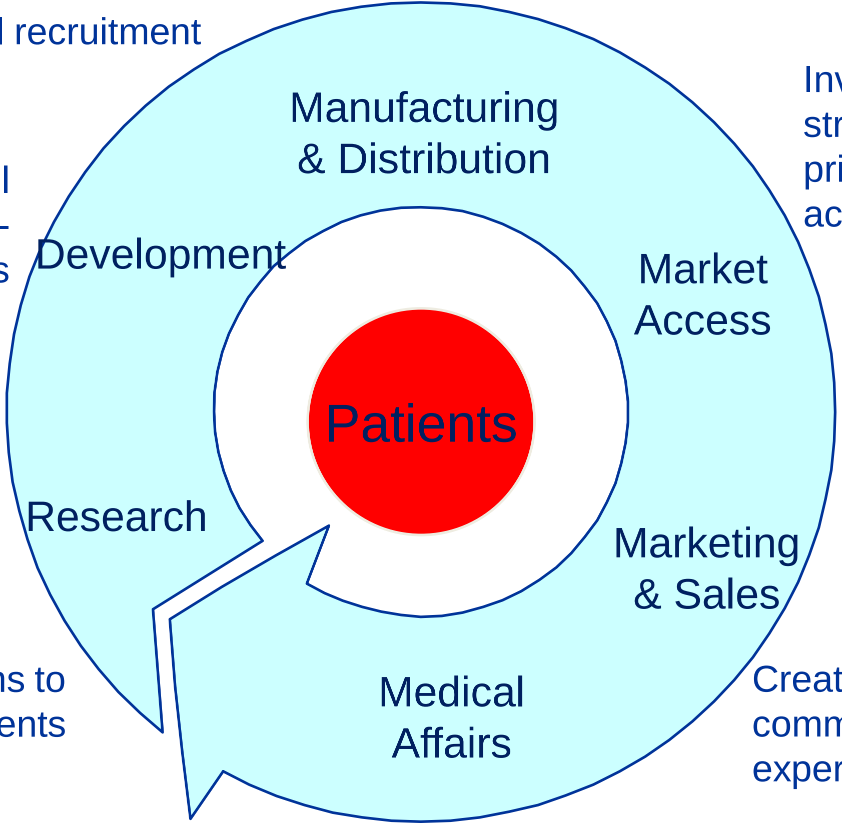
Patient-Centric Value Chain



Patients

Research

Development

Manufacturing & Distribution

Market Access

Marketing & Sales

Medical Affairs

Involve patient associations in clinical trial recruitment

Explore patient-centric distribution models

Build patient-friendly protocol design and define patient-relevant clinical endpoints

Involve patients in strategic discussions of price setting and market access approaches

Understand disease patient experience to better characterize unmet needs

Set up and train a dedicated reimbursement counseling staff

Develop tools to enrich physician/patient dialogue

Consult patient associations to determine economic requirements

Create virtual patient communities to facilitate experience-sharing

Train "Disease Champions" in a therapeutic domain in order to improve quality of care and compliance

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Dealing with Conflict of Interest

- You will always be criticized for taking industry money! I personally don’t think that this is in itself objectable…
- Whenever possible, highlight the Public Health objectives you both pursue
- Do not consistently represent a position that is useful to a single company, unless it is clear to all that patients will benefit
- Always frame your actions in complete operational and financial transparency

Practical Tips for Fund-Raising

- Approach companies well ahead of product launch in your country
- Inquire about the donor’s budget planning cycle
- Always contact pharma companies in late summer or early fall: before next year budget is locked in!
- If at all possible, agree on a multi-year program and obtain a multi-year commitment
- When possible, create an League for MS in your country where all pharma companies are represented and engage in common projects
- Think creatively beyond drug treatment: medical devices, imaging companies, disability accessories…

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Companies currently developing MS drugs

- Novartis: fingolimod (Gilenya) oral, approved
- Merck-Serono: cladribine (Mylinax) oral, Ph.III
- Teva/Active Biotech: laquinimod - oral, Ph. III
- Biogen-Idec: daclizumab (Zenapax) – IV, Ph.III
- Bayer/Genzyme: alemtuzumab (Campath) IV, Ph.III
- Roche: rituximab (Rituxan/MabThera) IV, Ph.II/III
- Opexa: cell therapy (Tovaxin) sub-Q, Ph.IIb
- J&J/Centocor: CNTO 1275 – sub-Q, Ph.II
- Roche/Biogen: ocrelizumab – IV, Ph.II
- GSK: firategrast – oral, Ph.II
- GSK: ofatumumab (Arzerra) Ph.II

Personal Relationships

- Most human relationships are based on personal contact and friendship, so get to know your key dialogue partner, but…
- The relationship between the industry partner and your group should not depend on one person, and end if that person moves on!
- Get to know the General Manager of the affiliate and invite more than one person from the company to advocacy events
- At the minimum, initiate a connection with both Marketing and Medical Affairs personnel

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Transparency

Increasingly (e.g. ABPI Code of Practice), all contributions to NGOs, and particularly patient organizations, must be disclosed (e.g. by posting them on company website: see among others http://www.gsk.com/responsibility/cr_issues/patient-organisations.htm or http://www.corporatecitizenship.novartis.com/patients/patient-partnership/patient-groups.shtml)

All agreements with patient groups should be documented in a written contract.

EFPIA Member Companies who voluntarily published list of sponsored patient groups on their website

Abbott Healthcare Products B.V.
Almirall
Amgen
Astellas Pharma Europe
AstraZeneca
Baxter
Bayer HealthCare
Boehringer Ingelheim
Bristol Myers Squibb
Chiesi Farmaceutici
Eli Lilly & Co
Laboratorios Dr Esteve
Genzyme
Gilead Sciences
GlaxoSmithKline
Grünenthal
Ipsen
Janssen-Cilag
H. Lundbeck
Merck Sharp & Dohme
Merck Serono
Novartis
Novo Nordisk
Orion Pharma
Pfizer-Wyeth
Hoffmann-La Roche
sanofi-aventis
Takeda
UCB-Pharma
VIFOR Pharma

Other EFPIA Member Companies make a list of sponsored patient groups available in a different format, or have no contacts with patient groups.

Data Protection and Data Privacy

- Any personal data on individual patients stored in a company database are subject to Directive 95/46/EC (need to inform data subject, right of access, right to object, reporting requirements, etc)
- This gives you and your members a measure of protection if you agree to expose individual patients to a particular company

Facts of Pharma Life

- “In this world nothing can be said to be certain, except **death and taxes**.“

  Benjamin Franklin
  Letter to Jean-Baptiste Leroy, 1789

- In the pharmaceutical world, nothing is certain, except **patent expiry and taxes**!
- Some of your sponsors will disappear, either because the drug they were hoping to launch has failed in clinical trials, or because generics have cannibalized their sales!
- You should be able to anticipate these things, and prepare for this eventuality…

Further Reading

- “An Essential Partnership: Principles and Guidelines for Working with Industry” published by the Association of Medical Research Charities

  http://www.amrc.org.uk/training--research-practice_working-with-industry

- “Guide to Sustainable Funding” published by the National Council for Voluntary Organisations

  http://www.ncvo-vol.org.uk/sfp