

**rx**mark

**rxmark**

*Introduction to rxmark & 10/10<sup>®</sup> 2001*

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**rxmark**

**A subsidiary of Wood, the global branding consultancy,  
providing research-based branding solutions to the pharmaceutical sector**

## Opening Thoughts ➔ *Subjectivity in Validation Studies*

**PROZAC**<sup>®</sup>  
fluoxetine hydrochloride

“For the majority of name validation studies, the *most preferred candidates* are often the names that are perceptually the most similar to well-known, *existing* brands...”

“Non-differentiated names, at first seemingly comfortable and familiar, are at best a missed opportunity, at worst given the present regulatory environment, untenable...”

**Propecia**<sup>®</sup>  
(finasteride)

**PROSCAR**<sup>®</sup>  
(FINASTERIDE)

**Protropin**<sup>®</sup>  
(somatrem for injection)

**PROCRIT**<sup>®</sup>

“Ultimately, brand names which do not challenge their intended audience often face a much more difficult task establishing brand equity...”

## rxmark → Who we are...

- The brand marketing research subsidiary of **Wood**
  - Wood is a leading pharmaceutical branding consultancy
    - Offices in New York, San Francisco and Geneva
  - rxmark provides research-based *branding solutions* to the pharmaceutical sector
    - **25%** of all projects are for non-Wood clients
    - Research **leader** for the evaluation of proposed pharmaceutical trademarks in the context of the global dispensing, marketing and regulatory environments
  - rxmark name validation services include:
    - 10/10® Trademark Evaluation Model
      - ↳ 10/10® Country Component // E.U. Upgrade
    - rxpersona
      - ↳ rxpersona **Consumer** & rxpersona **Corporate**
    - Conflict**F**ilter
    - Cross**C**ultural

## 'safety in numbers' ➔ rxmark 10/10® Select Portfolio



ED Treatment  
**Pfizer**



HIV Treatment  
**Abbott**



RA Treatment  
**Immunex**



Treatment for Overactive Bladder  
**Pharmacia**



UFH Treatment  
**Bristol-Myers Squibb**

The name validation methodology of choice for  
**over 50 FDA-approved pharmaceuticals including product introductions from  
Aventis, Bristol-Myers Squibb, Novartis, Pfizer, Pharmacia and Roche**

## 10/10® ⇨ A Balance of *Research & Consulting* Expertise

- Expertise in branding, fieldwork and analysis is required
  - Time = money in the context of your NDA/IND
    - A poorly researched result can **significantly** impact 'time to market'
- For many companies, the **need** for consulting services is present for the following:
  - Dispensing Issues
    - Greater awareness since the release of the *Institute of Medicine* report
  - Regulatory Issues
    - For the U.S., greater scrutiny since the creation of **OPDRA**
    - For Europe, greater scrutiny since the creation of the **EMEA**
  - Marketing Issues
    - Strategic branding issues
    - The need to reflect a multitude of languages and cultures for the development of both global and regional brands

## 10/10® ➡ Reflects Pharma Branding *Issues/Trends*

### ■ Dispensing environment **confusion**

#### □ Losec®/Lasix® Case Study

➔ Merck PPI originally marketed by Astra as Losec® in Europe

□ Lasix® misprescribed for Losec® due to visual similarity when scripted

□ Recall results in trademark switch to **Prilosec®**

### ■ FDA/EMEA rejection impacting ‘time to market’

□ FDA reveals **NDA/IND** rejections due to *unsuitable* tradenames at **30%**

➔ **LNC/OPDRA** guidelines/process never officially published/outlined

### ■ Client **uncertainty** as to what drives selection process

□ Focus ‘reactive’ to external ‘**physician preference**’

➔ Generic/therapeutic class encoding can result in **minimal** flexibility/value

□ Focus ‘proactive’ based on internal ‘**strategic marketing**’

➔ Differentiation may result in **greater** flexibility/value

## 10/10® Methodology = FDA & OPDRA Requirements

### ■ OPDRA Launched in Fall 1999 to **replace** the LNC

#### □ Office of Postmarketing Drug Risk Assessment

→ Mission: *“To increase the safe use of drug products by minimizing user error that is related to the naming, labeling and/or packaging of the product”.*

→ Jerry Phillips – Associate Director for Medication Errors

↳ Staff of four to conduct error prevention analysis and perform trend analyses

#### □ Multi-Factorial Concept for Review *based in part* using **established 10/10® methodologies** for name validation research

→ Established LNC Criteria

↳ Phonetic/Visual Similarity, etc.

→ Look-alike w/scripting and sound-alike evaluation

↳ Conducted internally

→ Computer-assisted evaluation (in development)

↳ Look Alike/Sound Alike orthographic string similarity

## rxmark ➔ 10/10<sup>®</sup> = *Added Value* **Benefits**

- A 10/10<sup>®</sup> *preliminary consultation* **maximizes the marketing opportunities** for your new compound and/or product pipeline
- A 10/10<sup>®</sup> *preliminary consultation* provides **flexibility** in the trademark selection process
  - To reflect a change in marketing status
    - ➔ Ensure that the entire candidate list is not tied to a single marketing strategy
  - To reflect a change in regulatory guidelines
    - ➔ Ensure that the candidate list can provide multiple brand names to meet regulatory requirements, e.g., present EMEA requirement for a distinct brand name to reflect each indication
    - ➔ Ensure that a candidate can support multiple indications to meet regulatory requirements, e.g., present FDA moratorium on multiple brand names for a single compound

## rxmark ➔ 10/10® = *Proactive Results*

- 10/10® **facilitates** the trademark selection process by creating an '**objective**' framework
  - Minimizes decisions based solely on '**subjective**' selection criteria
- Provides **answers** at a specific point in the branding process for the majority of trademark-related **concerns**
  - Can the candidate coexist with presently marketed and investigational brands?
    - ➔ Ability to be registered and protected as a trademark
    - ➔ Ability to be approved from a regulatory perspective
  - Is the candidate acceptable and appropriate from a global cultural, linguistic and marketing perspective?
    - ➔ Easy to communicate
    - ➔ Distinctive & memorable
    - ➔ Fulfill product 'lifecycle' objectives
  - Is the candidate acceptable to key internal decision makers?

## Introduction ➔ 10/10<sup>®</sup> Trademark Evaluation Model

**1**

**Phonetic Index**

**4**

**Verbal Velocity<sup>®</sup>**

**8**

**USAN/WHO**

**2**

**Visual Index**

**5**

**Cross Cultural**

**9**

**FDA/EMEA**

**3**

**Error Index<sup>®</sup>**

**6**

**rxpersona<sup>®</sup>**

**10**

**TM Registration**

**7**

**metanet**

...a name validation tool for the evaluation of future pharmaceutical trademarks

# 10/10® Configurations → Core Evaluation Services

## ■ 10/10® Market Configurations

### □ 10/10® North America

- Best choice for **U.S.-only** brands
- Includes U.S. physician & pharmacist sample

### □ 10/10® European Union

- Best choice for an **E.U.-only** brand
- Includes **single** E.U. market physician & pharmacist sample

### □ 10/10® North America & European Union (E.U. Upgrade)

- Best choice for **global** brands
- Includes U.S. sample + **single** E.U. market sample
- Full regulatory analysis - FDA/EMEA & USAN/WHO

### □ All market configurations

- rxpersona Corporate client company respondents
- Specialists optional
- Available in **Basic/Standard/Extended** sample configurations

# 10/10® → Core Services Overview

→ Sample Configurations	↓ Basic	↓ Standard	↓ Extended	
Market Configurations ↓	<b>10/10® N.A.</b>	<b>30 PCP</b>	<b>50 PCP</b>	<b>100 PCP</b>
	<input type="checkbox"/> Basic	<b>30 Pharmacists</b>	<b>50 Pharmacists</b>	<b>100 Pharmacists</b>
	<input type="checkbox"/> Standard	+ <b>4 Cross Cultural Analysts (North America only)</b>		
	<input type="checkbox"/> Extended	+ <b>2 Regulatory Analysts and 50 rxpersona Corporate (Client)</b>		
	<b>10/10® E.U.</b>	<b>30 PCP</b>	<b>50 PCP</b>	<b>100 PCP</b>
	<input type="checkbox"/> Basic	<b>30 Pharmacists</b>	<b>50 Pharmacists</b>	<b>100 Pharmacists</b>
	<input type="checkbox"/> Standard	+ <b>10 Cross Cultural Analysts (European Union only)</b>		
	<input type="checkbox"/> Extended	+ <b>2 Regulatory Analysts and 50 rxpersona Corporate (Client)</b>		
	<b>10/10® N.A./E.U.</b>	<b>30/30 PCP</b>	<b>50/50 PCP</b>	<b>100/100 PCP</b>
<input type="checkbox"/> Basic	<b>30/30 Pharmacists</b>	<b>50/50 Pharmacists</b>	<b>100/100 Pharmacists</b>	
<input type="checkbox"/> Standard	+ <b>6 = 10 Cross Cultural Analysts (North America &amp; European Union)</b>			
<input type="checkbox"/> Extended	+ <b>2 = 4 Regulatory Analysts and 100 rxpersona Corporate (Client)</b>			

## rxmark → Enhancement Evaluation Services

### ■ 10/10® CountryComponent and E.U. Upgrade

□ **Optional** on a per project basis

→ **30 to 100** PCP per market/sample configuration

↳ Specialists optional

→ **30 to 100** pharmacists per market/sample configuration

### ■ rxpersona Consumer

□ **Optional** on a per project basis

→ **60 to 250** patients/consumers per market/sample configuration

### ■ Cross Cultural Plus

□ **Optional** on a per project basis

→ Individual language/culture review

→ **E.U. Complete Bundle** adds **10** additional cultural/linguistic market reviews to upgrade **E.U. 10/10®** (totals **20**)

→ **E.U. Core Bundle** adds FR/DE/IT/PORT/SP/U.K. to upgrade **North America 10/10®** (totals **10**)

## rxmark → 10/10® CountryComponent :: E.U. Upgrade

- A market-specific **adaptation** of 10/10® that reflects the realities of *global branding*
  - Includes primary research with physicians and pharmacists from a single global market
    - Phonetic Index, Visual Index and Error Index® (for a single market)
    - rxpersona (for a single market)
  - E.U. Upgrade adds additional 10/10® elements related to E.U.-specific cultural/linguistic and regulatory concerns
    - Cross Cultural (E.U. Upgrade adds six E.U. languages)
    - EMEA & WHO (E.U. Upgrade adds regulatory analysis)
  - A CountryComponent E.U. Upgrade can consist of the following E.U. markets as the upgrade market:
    - France or Germany
  - Purchase CountryComponent(s) for global markets to complement the purchase of the E.U. Upgrade and to broaden the scope of the study

## rxmark → rxpersona **Consumer**

- A respondent-specific **adaptation** of 10/10® that reflects the realities of *direct-to-consumer marketing*
  - rxpersona **Consumer** measures consumer/patient ratings and prefs for attributes/candidate
    - Initial Impression/Associations
    - Distinctiveness
    - Compatibility/Communication :: Core Concept
    - Compatibility/Communication :: Class/Product Profile
    - Personal Consideration
- **Consumer** respondents can *validate* consumer-driven branding strategies or *identify* potential concerns or considerations **meaningful** to the consumer audience
  - Survey/sample can be **customized** to reflect project objectives
  - **Basic** sample configuration
    - **60** patients/consumers per market

## rxmark → rxpersona **Corporate**

- A respondent-specific **adaptation** of 10/10® that reflects the realities of *internal consensus building*
  - rxpersona **Corporate** measures internal client company participant ratings and prefs for attributes/candidate
    - Initial Impression/Associations
    - Distinctiveness
    - Compatibility/Communication :: Core Concept
    - Compatibility/Communication :: Class/Product Profile
    - Personal Consideration
- **Internal participants can identify** unforeseen hurdles or considerations known only to those with access to confidential/limited internal/external information
  - Survey/sample can be **customized** to reflect project objectives
  - **Flexible** sample **inclusive** with all 10/10® projects

# rxmark → Enhancement Services Overview

→ Sample Configurations	↓ Basic	↓ Standard	↓ Extended
<b>10/10® C2</b> <input type="checkbox"/> Basic <input type="checkbox"/> Standard <input type="checkbox"/> Extended	30 PCP	50 PCP	100 PCP
	30 Pharmacists	50 Pharmacists	100 Pharmacists
<b>rxp Consumer</b> <input type="checkbox"/> Basic <input type="checkbox"/> Standard <input type="checkbox"/> Extended	60 Patient/Cons.	100 Patient/Cons.	250 Patient/Cons.
<b>Cross Cultural +</b> <input type="checkbox"/> Basic (Single) <input type="checkbox"/> Standard (Core) <input type="checkbox"/> Extended (Complete)	1 Market/Language	6 Markets/Languages	10 Markets/Languages

## rxmark **Benefits** ➔ The Decision for **10/10®**

- **10/10®** delivers analysis from the ‘**brand**’ perspective:
  - **15** years of brand consulting **expertise** with virtually every major pharmaceutical company
  - Research **leadership** in a highly-specialized field
    - ➔ First to place strategic marketing **above** physician preference
    - ➔ First to stress **proactive** approach to dispensing/regulatory issues
- Cost, Time and Resource **Effectiveness**
  - ‘**Best of breed**’ dispensing, regulatory and cultural/linguistic analysts
  - Projects **completed** in a span of four to seven weeks
  - **Collaborative relationship-building** with client marketing and market research departments to resolve the ‘**branding**’ challenge
- Only **10/10®** provides each project a customizable comparative context using the **10/10® Index** benchmarks
  - **400+** pharmaceutical brand name evaluations comprised of **3000+** brand name candidates completed over the past ten years

## rxmark Benefits → SOP Considerations

- Do you require a *global brand*?
  - If so, do you require consensus by **country affiliates**?
  - For which market(s) is it practical to conduct primary physician and pharmacist research? The **leading** market or the **top** four or five?
  - For smaller markets is **cultural and linguistic suitability** sufficient?
- Do you require *consumer* validation to make a decision?
  - If so, **who**, how large a **sample** and in which **markets**?
- What are your *trademark* requirements?
  - A **single** trademark or **multiple** trademarks?
- What size of *sample* or type of *specialists* do you require to secure *internal consensus*?
  - The **basic** sample for all markets?
  - The **standard** or **extended** sample in your leading market(s)?
  - **Specialists** where appropriate?

## Parting Thoughts ➔ “No Time Like Today”



Merck

**“During the first *four* months of this year, Merck spent \$67 million to advertise Vioxx to consumers...”**

*New York Times – 10.5.00*

**“While drug companies once waited for sales of a new drug to gradually take off, they must now sell as much of a drug as possible...”**

*New York Times – 10.5.00*



Pharmacia

***“In the history of the pharmaceutical industry, no other drugs have earned more money for their makers in their first year on the market... the companies expect to sell about \$4 billion worth of the painkillers this year.”***

*New York Times – 10.5.00*

# rxmark

## Brand & Client **Portfolio 2001**

*Our portfolio, drawn from the leading brands and respective marketers in the healthcare sector, reflects the growing number of companies who have concluded a comprehensive, systematic approach to pharmaceutical trademark evaluation is an essential component of any successful product launch.*

# Brand Portfolio *Analgesics*

■ Brand	□ Description	→ Client
<b>Actiq</b>	Narcotic > Oral Opioid	<b>Anesta</b>
<b>Axert</b>	Migraine	<b>Pharmacia</b>
<b>Celebrex</b>	NSAID > COX-2 Inhibitor	<b>Pharmacia (Searle)</b>
<b>Maxalt</b>	Migraine	<b>Merck</b>
<b>Relpax</b>	Migraine	<b>Pfizer</b>
<b>Zomig</b>	Migraine	<b>AstraZeneca</b>

# Brand Portfolio *Antimicrobials*

■ Brand	□ Description	→ Client
<b>Aldara</b>	Anti-Viral/Dermatologic	<b>3M</b>
<b>Kaletra</b>	Anti-Viral > HIV	<b>Abbott</b>
<b>Mepron</b>	Anti-Parasitic	<b>Glaxo SmithKline</b>
<b>Ocutide</b>	Anti-Viral	<b>Gilead Sciences</b>
<b>Valtrex</b>	Anti-Viral > Herpes	<b>Glaxo SmithKline</b>
<b>Valcyte</b>	Anti-Viral > HIV	<b>Roche</b>
<b>Vistide</b>	Anti-Viral > CMV	<b>Gilead Sciences</b>
<b>Zerit</b>	Anti-Viral > HIV	<b>Bristol-Myers Squibb</b>

# Brand Portfolio Cardiovascular (ACE)

■ Brand	□ Description	→ Client
Co-Aprovel	ACE-I/A2Rs (combo)	Bristol-Myers Squibb/Sanofi
Co-Diovan	ACE-I/A2Rs (combo)	Novartis
Cozaar	ACE-I/A2R-antagonists	Merck
Diovan	ACE-I/A2R-antagonists	Novartis
Hyzaar	ACE-I/A2Rs (combo)	Merck
Lotrel	ACE-I/A2Rs (combo)	Novartis
Mavik	ACE-I/A2R-antagonists	Knoll
Tarka	ACE-1/A2Rs (combo)	Knoll

# Brand Portfolio *Cardiovascular (Other)*

■ Brand	□ Description	→ Client
<b>Dermadex</b>	Diuretic	<b>Roche/Boehringer Mannheim</b>
<b>Tikosyn</b>	Anti-Arrhythmic	<b>Pfizer</b>

# Brand Portfolio Hematology/Oncology

■ Brand	□ Description	→ Client
<b>Afema/Femara</b>	Hormonal Oncologic	<b>Novartis</b>
<b>Incel</b>	Multidrug Resistance Inhibitor	<b>Vertex</b>
<b>Iressa</b>	TK Inhibitor	<b>AstraZeneca</b>
<b>Mabthera</b>	Lymphoma (NHL) Treatment	<b>Roche</b>
<b>Mobista</b>	Flt3 Ligand	<b>Immunex</b>
<b>Optro</b>	Blood Substitute	<b>Baxter (Somatogen)</b>
<b>Segard</b>	Sepsis Treatment	<b>Knoll</b>
<b>Xeloda</b>	Hormonal Oncologic	<b>Roche</b>
<b>Ellence</b>	Hormonal Oncologic	<b>Pharmacia</b>

# Brand Portfolio *Neurologic/Psychiatric*

■ Brand	□ Description	→ Client
<b>Carbex</b>	Anti-Parkinson	<b>Du Pont</b>
<b>Effexor</b>	Anti-Depressant	<b>Wyeth</b>
<b>Geodon</b>	Anti-Psychotic	<b>Pfizer</b>
<b>Remeron <i>SolTab</i></b>	Anti-Depressant Form Extension	<b>Organon</b>
<b>ReVia</b>	Alcohol/Drug Cessation	<b>Du Pont</b>
<b>Sonata</b>	Anxiolytic/Hypnotic > Insomnia	<b>Wyeth</b>
<b>Tasmar</b>	Anti-Parkinson	<b>Roche</b>

# Brand Portfolio General

■ Brand	□ Description	→ Client
<b>Andros</b>	Controlled Release Delivery System	<b>Baxter</b> (Somatogen)
<b>Arava</b>	RA	<b>Aventis</b>
<b>Comvax</b>	Combination Vaccine	<b>Merck</b>
<b>Cosopt</b>	Ophthalmic Combination Treatment	<b>Merck</b>
<b>Propecia</b>	Male Pattern Baldness Treatment	<b>Merck</b>
<b>Levlite</b>	Contraceptive	<b>Berlex</b>
<b>Lymerix</b>	Lyme Disease Vaccine	<b>Glaxo SmithKline</b>
<b>Nimbex</b>	Anesthesia > Neuromusclar Blockers	<b>Glaxo SmithKline</b>

# Brand Portfolio General

■ Brand	□ Description	→ Client
<b>Estring</b>	Estrogen Delivery	<b>Kabi Pharmacia</b>
<b>Protonix</b>	PPI	<b>Wyeth</b>
<b>Qvar</b>	CFC-Free Asthma Inhaler	<b>3M</b>
<b>Sequus</b>	Corporate ID	<b>Liposome Technologies</b>
<b>Singulair</b>	Asthma Treatment	<b>Merck</b>
<b>Trocade</b>	Anti-Rheumatic	<b>Roche</b>
<b>Viagra</b>	Erectile Dysfunction	<b>Pfizer</b>
<b>Vivelle</b>	HRT Transdermal Matrix Patch	<b>Novartis</b>

# Client Portfolio :: A C

**■ Client**

**□ 10/10® Certified**

3M

Aldara, Qvar

Abbott

Kaletra

Anesta

Actiq

AstraZeneca

Iressa, Zomig

Aventis

Arava

Baxter (Somatogen)

Andros, Optro

Berlex

Levlite

Boehringer Mannheim

Demadex

Bristol-Myers Squibb

COAprovel, Vaniqa, Zerit

# Client Portfolio :: D L

## ■ Client

## □ 10/10® Certified

Du Pont

Carbex, ReVia

Gilead Sciences

Ocutide, Vistide

Glaxo SmithKline

Lymerix, Mepron, Nimbex, Valtrex

Immunex

Enbrel, Mobista

Kabi Pharmacia

Estring

Knoll

Mavik, Segard, Tarka

Liposome Tech.

Sequus Pharmaceuticals Corp.

# Client Portfolio :: M Z

## ■ Client

## □ 10/10® Certified

**Merck**

**Aggrestat, Comvax, Cosopt, Cozaar, Hyzaar,**

**Maxalt, Propecia, Singulair, Vaqta**

**Novartis**

**Afema/Femara, Co-Diovan, Diovan, Lotrel, Vivelle**

**Organon**

**Remeron *Sol Tabs***

**Pfizer**

**Geodon, Relpax, Tikosyn, Viagra**

**Pharmacia/Searle**

**Axert, Celebrex, Detrol LA, Ellence**

**Roche**

**MabThera, Tasmar, Trocade, Valcyte, Xeloda**

**Vertex**

**Incel**

**Wyeth**

**Effexor, Protonix, Sonata/Soluna**