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Working towards a reliable, reversible male contraceptive injectable implant
Men do not have access to a reliable and reversible male contraceptive

Men need access to a reliable, reversible male contraceptive that enables them to control their fertility and to actively participate in family planning. Yet no such reversible male contraceptive exists. Many couples, as well as doctors, are frustrated by the lack of a reliable and reversible male contraceptive.

Many women are unable or unwilling to use the available female contraceptive methods for their entire reproductive life; women should not be exclusively burdened with the responsibility of contraception, both men and women should be able to share the benefits and burdens of family planning.

There is no “male pill” – no such product is being trialled and there is unlikely to be one for many years. This is because the chemicals that are needed to suppress men’s sperm output cannot be given in a safe oral form – however implants and long acting injectable products have shown great promise.

When it comes to currently available male contraceptives, the reversible methods are not reliable and the reliable methods are not considered reversible

In reality, the only reversible contraceptive options available to men are the condom and the withdrawal method – and both methods are unreliable and unacceptable for many couples.

Non-use or misuse of condoms and other natural family planning methods, even by ‘experienced’ couples, has a high contraceptive failure rate. On the other hand, vasectomy is a very effective form of contraception but it cannot be considered a reversible way to control male fertility. Vasectomy reversal is complex, expensive and not always successful. When vasectomy reversal fails, female partners have to undergo IVF treatment using sperm surgically retrieved from their partners; again, this is complex, expensive and success rates vary.

Scientists have discovered that an effective and reversible male contraceptive is possible

Decades of research performed by medical researchers, supported by public sector research funding organisations, including the World Health Organisation and industry, have discovered that hormone-based male contraceptives are highly effective, reversible, well tolerated and likely to be as safe as female contraception. Many prototype products trialled so far work as effectively as the female oral contraceptive (“the Pill”). In most studies the contraceptive has been almost as effective as vasectomy; but unlike vasectomy, it is fully reversible.

Why isn’t a reversible male contraceptive on the market?

The failure to bring a reversible hormone-based male contraceptive to the market is mainly due to problems with the available products. Although effective in clinical trials, current prototypes have not been convenient to use (e.g. requiring frequent injections, not long-acting enough) nor have they always provided the stable male hormone levels required to limit side effects.
Simply put, the pharmaceutical industry is no longer willing to commit the time and money to develop the ideal product to bring to the market, preferring more lucrative sectors. The development of new hormone-based contraceptives is seen to be too costly and higher risk; the industry would prefer to invest in lower risk/higher profit medicines, such as drugs to treat common, long-term, mostly incurable diseases like cancer and heart disease.

How we will discover the new reversible male contraceptive

Androfin is a not-for-profit organisation that was born out of the recognition of a need for a new approach to bring a reversible male contraceptive to the world. We have gathered together world-leading scientists and clinicians in male contraceptive research to identify a new and reversible contraceptive.

We have identified a targeted project that will capitalise on years of expertise and information to discover the “ideal” hormone-based product.

We will perform all the necessary pre-clinical and clinical testing required to bring the product to the market.

Our goal is to produce a long acting contraceptive implant that will prevent a man from making sperm

We will harness the skills of our world-renowned scientists and clinicians to discover, develop and test a contraceptive that can be implanted under a man’s skin and prevent his testes from making sperm.

While we know the current formulations work effectively, our strategy will enable us to discover a better product that is easier to use and has minimal and acceptable side effects.

The compound we need to find probably already exists, as thousands of potentially suitable compounds have been produced over the past half century. Our goal is to identify the best compound and formulate this into a long acting implant. This product is unlikely to be patentable however this situation will be different if a novel compound is invented.

We have the knowledge, expertise and strategy and seek the funding to turn a reversible male contraceptive from a possibility into a reality

Androfin has strategically assembled some of the best researchers and clinicians in the world to tackle this problem. Now we need to draw together donors to support this ground breaking research project and enable us to bring a new contraceptive option to the other half of the population.
As more and more couples choose to delay having children until their late twenties and thirties, there is an increasing reliance on reversible contraceptives.

For decades now, women have had access to reliable and reversible contraceptive methods (such as the Pill and IUDs), yet no such reliable, reversible contraceptive exists for men. Men want to participate in family planning too but have only limited options available to them; condoms, the withdrawal method and vasectomy.

While vasectomy is reliable, it cannot be considered reversible in practice – it is only recommended for men who have completed their family.

For those wanting to delay parenthood, the withdrawal method has a high failure rate and the only mechanical aid is the condom. Both methods are unpopular for loss of sensation and inconvenience. While condoms work for protection against sexually transmitted diseases (with very heavy marketing to overcome their unpopularity), they are not widely suitable or popular for regular family planning for couples in stable relationships.

Despite the limited options available, at least a third of all men participate in contraception. Men have a desire to control their own fertility, to share the burden of contraception with their partner and to actively participate in family planning.

Unlike women, men do not go through menopause and, barring ill-health, remain fertile for the rest of their lives.

Given their very long reproductive life span and the growing frequency of remarriage, men should be able to access a wide range of contraceptives to control their fertility.

Clinical and epidemiological studies show that, should a reliable and reversible contraceptive be available, men would use it. At least a quarter of men worldwide – and more than half in many countries – would consider using a reversible contraceptive. More than 80% of men involved in the last World Health Organisation (WHO) trial indicated they would be interested in continuing.

Studies also show that female partners would be happy to rely on it too, with the vast majority of women saying that they would trust their partner to use it. This is quite consistent with the fact that women rely on their partner’s vasectomy as a contraceptive even when no sign of it is visible.

The global case for a new male contraceptive†

- Over 40% of pregnancies worldwide are unintended
- More than half of these pregnancies end in termination
- The rates of unintended pregnancies and terminations are even higher in developing countries
- A third of all couples using contraception rely on the male partner’s participation
- The World Health Organisation has long recognised the global need for a reversible male contraceptive

† Statistics from the World Health Organisation
Decades of research have shown a hormone-based method is the most promising approach to an effective and reversible male contraceptive.

The optimal formulation uses the hormones androgen (such as testosterone) and progestin. Years of research and accumulation of data makes a hormone-based product the most practical approach to pursue to bring the first reversible male contraceptive to the market.

One day we hope that men will have access to a range of contraceptives. However hormone-based contraception is the only method so far that has been demonstrated to be safe, effective and reversible in men. It remains the most advanced, realistic and practical approach to pursue to bring the first reversible male contraceptive to the world.

### Other approaches to male contraceptive development

Women have a variety of contraceptives available to them, ranging from the oral contraceptive pill, hormone implants and intrauterine devices. Men have only condom and vasectomy. Various approaches to male contraception are currently being investigated. For example:

- **Vasalgel** (based on a technology called RISUG) is a gel injected into the vas deferens to block sperm from entering the ejaculate. At this point, there are limited human studies and its reversibility has not been demonstrated; until then, it should be considered as a vasectomy alternative, rather than a reversible means of contraception.

- Various research projects have investigated chemical (non-hormonal) compounds that could reversibly block production of sperm within the testes or inhibit sperm fertilising function. However these experiments have only been conducted in mice and none have reached the stage of clinical testing. Whether such agents can be safely and effectively used as a contraceptive in humans has not been established and is a long way from reality.

### Timeline of male hormonal contraceptive development

**1960s-1970s**
- The female contraceptive pill is introduced
- The World Health Organisation (WHO) recognises that male contraceptives are also required
- Clinical trials show that androgen +/- progestin can halt sperm production in men

**1980s-1990s**
- WHO multicentre trials conclude androgen-based contraceptives are highly effective at preventing pregnancy
- Androfin’s clinicians lead clinical trials showing that androgen and progestin combinations are faster acting and more effective than androgen alone

**2000s & beyond**
- Androfin scientists perform a meta-analysis of 30 contraceptive trials showing that androgen + progestin contraception is fully reversible within a practical timeframe
- Studies on more than 9000 men across 4 continents show that more than half would use a hormone-based contraceptive
- Studies on androgen and progestin formulations continue, but the ‘ideal’ formulation has not yet been achieved
Many men would be willing to use such a contraceptive and would be supported by their female partners. A reversible male contraceptive approach has been identified that delivers low doses of androgens (male hormones, principally testosterone) with a progestin (a type of progesterone, the hormone of pregnancy, found in female contraceptive agents) to suppress sperm production while also maintaining normal androgen effects in the body. Sperm counts are suppressed for as long as the contraceptive is used and then naturally recover after the method is stopped. Depot (prolonged release) combination androgen-progestin regimes show particular promise.

Over 10 years ago, Androfin’s clinicians were the first in the world to demonstrate the feasibility and contraceptive effectiveness of this approach in humans; this work served as the model for later worldwide studies by the World Health Organisation.

It works.
Up to 98% of men achieve effective sperm count suppression to a level that is suitable for reliable contraception. Although sperm production in the testes is halted, all sexual functions, including erections and ejaculation, are unaffected.

And it works well.
Nearly all men achieve sperm counts so low that it offers excellent contraceptive cover – as good as vasectomy and the female pill. Like vasectomy, the male contraceptive takes about 2-3 months to be fully effective while sperm are cleared out from the man’s reproductive system. And when men cease the contraceptive, sperm output and fertility recover in a predictable time frame. So far this approach is the only reliable contraceptive ever shown to be fully reversible in men.

It is well tolerated.
Four decades of studies have consistently shown that short to medium term hormone-based contraceptives are associated with only minor nuisance side effects: the specific side effects vary with the prototype but are mainly mild, such as increased libido, mood changes, acne, weight gain (some due to increased muscle mass) and increases in haemoglobin levels. Few men have dropped out of the contraceptive trials – a small proportion (~2%) of men have to discontinue treatment if their sperm counts are not fully suppressed so there is a need to check once (after a few months) how effectively the contraceptive is working; as is the case for vasectomy. The pattern of side-effects of a male hormonal contraceptive is quite comparable with those well established for female hormonal contraceptives.

So... what’s the problem?
The “perfect” product has yet to be identified. The type of product influences its acceptability to men in terms of side effects and how often it is administered. A key point is that products that are given more frequently produce initial “bursts” of hormones in the blood, before the hormones are metabolised by the body. It is these bursts of higher than normal levels that tend to cause side effects – although most of the side effects seen are similar to those experienced by women taking the female oral contraceptive. The fewer the side effects, the better the product. A product that is longer acting and does not produce these initial “bursts” of hormones would produce fewer side effects and be given to men more easily.

The optimal product composition in terms of delivery and side effect profile still needs to be invented.
Why isn’t the pharmaceutical industry supporting this?

The failure to bring a reversible hormone-based male contraceptive to the market is mainly due to the lack of a suitable product. Male hormone-based contraception suffered a major setback in the mid-2000s when the pharmaceutical companies involved in product development withdrew their support based on several business case concerns.

The development of new hormone-based contraceptives are seen to be costly and high risk, when compared with drugs for cancer or heart disease. Cited concerns from the industry have included low profitability compared with female contraceptives, and their perception of possible unwillingness of men and their partners to rely on a male contraceptive, even though research (including by companies) disproves these concerns. They have also expressed concern about the risk of litigation regarding potential harm to otherwise healthy people, yet such concerns have been managed in regard to every new female contraceptive for decades (plus some other drugs like blood pressure medications, statins, Propecia and Viagra).

Due to the lack of industry support, the discovery of new male contraceptives rest in the hands of not-for-profit and charitable organisations.
Years of research has shown that combined androgen and progestin can be used as a safe, effective and reversible hormonal male contraceptive.

In order to bring such a contraceptive to market, an optimised product needs to be identified.

While the pharmaceutical industry is no longer committed to the invention of new products for hormonal male contraception, there is a substantial worldwide market for a reliable, reversible male contraceptive. The global community now awaits the development of the suitable product – one that minimises side effects and that can be delivered in a way men will find easy to use.

The best prototypes trialled so far involve the use of an androgen (a male hormone, usually testosterone but also synthetic androgens based on a modified form of testosterone) and a progestin (synthetic forms of progesterone).

We already know that androgens can be effectively given to men in doses that suppress sperm production. Testosterone is widely used in men with testosterone deficiency, for example due to testicular damage, and is very effective and well accepted with few side effects: the doses used in these men are similar to those used for contraceptive suppression. We also know that progestins can be used in men to suppress sperm production, and they have been used with few side effects.

How does the male contraceptive work?

The contraceptive is made up of the hormones, androgen and progestin. These hormones are released from an implant into the blood and in turn act on the pituitary gland to block the release of hormones required to stimulate the testes to produce sperm.

Although sperm production is halted, all other functions in men are maintained, including androgen actions in the body and all sexual functions including erections and ejaculation.

The optimal formulation:

- Achieves stable levels in blood
- Is long acting over many months
- Has limited side effects
- Produces effective and reversible sperm suppression
The best measure of whether a hormone-based contraceptive works in men is quite simple – counting the number of sperm in a semen sample. A man’s sperm count allows his doctor to assess how quickly and fully he is responding to the contraceptive.

Once a man’s sperm count has suppressed to a certain level, the contraceptive effect is as least as good as, and potentially even better than, other currently available reversible methods such as the female “Pill”.

We know what levels to aim for: sperm counts that are zero or less than 1 million per millilitre is achievable in virtually all men (the average level is around 50 million per millilitre).

For men who use a hormonal male contraceptive, we know that sperm output and fertility will recover after the contraceptive is ceased.

When developing new products, the aim is to identify those that are the fastest, most complete and reversible in term of sperm count suppression.

Combined androgen and progestin products are the fastest acting and most effective prototypes trialled so far.

Based on trials of different prototypes, this contraceptive is expected to be as reliable as female contraception and could even be as effective as vasectomy in many men.

Slow release, long acting formulations would limit side effects and be better tolerated by men in terms of acceptability and ease of use.

What we know...

- The best measure of whether a hormone-based contraceptive works in men is quite simple – counting the number of sperm in a semen sample. A man’s sperm count allows his doctor to assess how quickly and fully he is responding to the contraceptive.
- Once a man’s sperm count has suppressed to a certain level, the contraceptive effect is as least as good as, and potentially even better than, other currently available reversible methods such as the female “Pill”.
- We know what levels to aim for: sperm counts that are zero or less than 1 million per millilitre is achievable in virtually all men (the average level is around 50 million per millilitre).
- For men who use a hormonal male contraceptive, we know that sperm output and fertility will recover after the contraceptive is ceased.
- When developing new products, the aim is to identify those that are the fastest, most complete and reversible in term of sperm count suppression.
- Combined androgen and progestin products are the fastest acting and most effective prototypes trialled so far.
- Based on trials of different prototypes, this contraceptive is expected to be as reliable as female contraception and could even be as effective as vasectomy in many men.
- Slow release, long acting formulations would limit side effects and be better tolerated by men in terms of acceptability and ease of use.
Discovery Phase

Our goal: to discover the optimal reversible male contraceptive product

The discovery phase of the project will identify a single compound that can act as both an androgen and a progestin, and that can be administered via a long acting implant.

We are looking for a compound that will:
- Have the best features of the androgen and progestin formulations that we know reversibly suppress sperm counts in men
- Be slowly released from an implant and will be long acting
- Produce an excellent contraceptive effect with limited and acceptable side effects

Discovery phase at a glance: 30 month accelerated program

<table>
<thead>
<tr>
<th>Year 1</th>
<th>Year 2 - 3</th>
<th>Year 2 - 3</th>
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</thead>
<tbody>
<tr>
<td>Lead compound discovery</td>
<td>Larger scale production</td>
<td>Implant formulation</td>
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</table>

- Expert chemists will examine the structure of thousands of compounds and identify those that can act as an androgen and progestin. In part, this will involve review of large publicly available databases listing hundreds of molecules and their known effects.
- Compounds will screened for androgen/progestin action in vitro (in isolated cell lines)
- Compounds will be screened for their ability to be released from implants
- Initial in vivo testing will be performed

- The most promising candidate compounds will be produced in larger amounts and further tested in vivo to verify effectiveness, reversibility and tolerability
- Pre-clinical toxicology testing will be performed to verify the lack of unexpected side effects and show that sperm suppression is effective, long-lasting and reversible
- One or two of the best compounds will be formulated into a sterile implant, under strict manufacturing conditions, to produce a product that is able to be tested in humans
### Discovery Phase - $6.5 million

<table>
<thead>
<tr>
<th>Task Description</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Staffing</th>
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<tbody>
<tr>
<td>1. Identify lead compounds from a series of candidates</td>
<td></td>
<td></td>
<td></td>
<td>$3m</td>
</tr>
<tr>
<td>1.A Screen medical and patent literature for synthetic androgens and progestins to identify candidates or leads for candidates. Decision to select a known chemical or commission synthesis of a new lead candidate.</td>
<td></td>
<td></td>
<td></td>
<td>1 x programme manager</td>
</tr>
<tr>
<td>1.B Establish yeast androgen and progesterin receptor in vitro bioassays for screening. Screen leading candidates.</td>
<td></td>
<td></td>
<td></td>
<td>1 x experienced postdoctoral scientist with organic chemistry and patent searching expertise</td>
</tr>
<tr>
<td>1.C Evaluate release characteristics of candidates from implant materials.</td>
<td></td>
<td></td>
<td></td>
<td>1 x experienced postdoctoral scientist with biological expertise</td>
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<tr>
<td>1.D Preliminary in vivo testing of lead candidates.</td>
<td></td>
<td></td>
<td></td>
<td>2 x research assistants</td>
</tr>
<tr>
<td>1.E Further in vivo testing of lead candidates in other models.</td>
<td></td>
<td></td>
<td></td>
<td>Consumables $30k per lab person per year</td>
</tr>
<tr>
<td>2. Commission new steroid synthesis</td>
<td></td>
<td>$1.5m</td>
<td></td>
<td>Consultant and commissioned work in organic chemistry</td>
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<tr>
<td>3. Toxicology testing</td>
<td></td>
<td>$1m</td>
<td></td>
<td>Commissioned external toxicology</td>
</tr>
<tr>
<td>4. Pharmaceutical chemistry development of sterile GMP product for clinical use</td>
<td></td>
<td>$1m</td>
<td></td>
<td>Consultant and commissioned work in pharmaceutical chemistry</td>
</tr>
</tbody>
</table>
Final Phase: Clinical Trials

Once we have created the contraceptive implant, it will be tested in men to demonstrate its use as a safe, effective and reversible male contraceptive.

Clinical trials will begin in year 3. These trials are designed to produce the necessary clinical data required for the product to be registered for marketing.

Our team are very experienced in such studies, with 30 years of experience in this area and in related fields of endocrinology, with due regard to all procedural and human ethics oversight.

Clinical Testing Phase - $13.5 million

Staff Costs
$3.36m Trial site/centre managers ($120k p.a. x 4 managers x 7 yrs)
$1.26m Project manager ($180k p.a. x 1 manager x 7 yrs)
$1.2m Data & biostatistics manager ($170k p.a. x 1 manager x 7 yrs)

Other Costs
$1m Centralised centre co-ordinator meetings ($150k p.a. x 7 yrs)
## Androfin Time Line and Use of Funds

<table>
<thead>
<tr>
<th>Androfin Foundation</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
<th>Year 6</th>
<th>Year 7</th>
<th>Year 8</th>
<th>Year 9</th>
<th>Participant details</th>
</tr>
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<tbody>
<tr>
<td>DISCOVERY PHASE</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>$6.5m</td>
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<tr>
<td>CLINICAL TESTING PHASE</td>
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<td></td>
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<td>$13.5m</td>
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</tbody>
</table>
| PHASE I             |        |        |        |        |        |        |        |        |        | Participants: 8 men  
|                    |        |        |        |        |        |        |        |        |        | Patient costs: $10k |
| PHASE I/II          |        |        |        |        |        |        |        |        |        | Participants: 32 men 
|                    |        |        |        |        |        |        |        |        |        | Patient costs: $40k |
| PHASE II            |        |        |        |        |        |        |        |        |        | Participants: 30 men 
|                    |        |        |        |        |        |        |        |        |        | Patient costs: $75k |
| PHASE IIIA          |        |        |        |        |        |        |        |        |        | Participants: 40 men 
|                    |        |        |        |        |        |        |        |        |        | Patient costs: $300k |
| PHASE IIIIB         |        |        |        |        |        |        |        |        |        | Participants: 400 men 
|                    |        |        |        |        |        |        |        |        |        | Patient costs: $6m   |
About Androfin
The Scientists

Professor David Handelsman
MB BS (Melb) PhD (Syd) FRACP FAHMS

Prof Handelsman is a physician-scientist specialising in male reproductive health, androgen biochemistry and contraception.

He is Professor of Reproductive Endocrinology and Andrology, founding Director of the ANZAC Research Institute and of Australia’s first Andrology Department at Concord Hospital. He is an international leader in the field of androgen physiology and pharmacology and has served on committees such as the WHO Human Reproduction Program and the World Anti-Doping Agency. Over the last 3 decades he has been closely involved in all major international multi-centre male contraception clinical trials including designing, monitoring and drafting the manuscripts for the two landmark WHO male contraception studies. In Australia he directed many Australian path-finding studies and clinical trials for male contraception including designing and directing the original proof-of-principle study for a depot androgen and progestin male contraceptive.

Professor Robert I McLachlan
MB BS (Monash), PhD (Monash), FRACP AM

Prof McLachlan is a physician-scientist specialising in male reproductive health, infertility and contraception.

He is Director of Clinical Research at the Hudson Institute of Medical Research, Deputy Director of Endocrinology at Monash Health, Consultant Andrologist at Monash IVF and Director of Andrology Australia. His work has improved clinical practice and health promotion in men’s health, and he has provided advice to government and industry on numerous issues. He is a member of two World Health Organisation taskforces, including one on “Male Fertility Regulation”.

He has led and participated in numerous hormone-based male contraceptive trials, including those that have assessed the direct impact of such contraceptives on sperm production, and the effects of combined androgen and progestin contraceptives.
Product Development

Benefits

Life stages of male contraceptive use

Extensive surveys of thousands of men worldwide show that a majority of men would consider using a reversible male contraceptive. As men have such long reproductive lifespans and are capable of fathering children for most of their lives, there are many times throughout a man’s life where the ability to control their own fertility would be desirable:

– Teenagers, where the risk of unplanned pregnancy is high
– University students and young men in their twenties who wish to control their own fertility
– Single men in casual relationships wishing to avoid the emotional and financial costs associated with unplanned pregnancies
– Couples who wish to delay parenthood, especially where the female partner is unwilling or unable to take a female contraceptive
– Couples wanting contraception after the birth of a child, when breastfeeding can limit the type of contraception that women can take
– Couples who have finished having children, but do not wish to use an irreversible form of contraception such as vasectomy
– Older men who seek to control their fertility, for example men entering into a new relationship after the breakdown of a long term relationship
– All men wanting to delay reproduction

Improved access to contraception and family planning has far reaching benefits:

● **Empowering people and enhancing their education.** Family planning allows men and women to make choices about their reproductive health and their family. Family planning can give both women and men better opportunities to participate in education, paid employment and public life. Children from families with better access to family planning tend to stay in school longer and have better long term outcomes.

● **Improving the well being of people living in vulnerable communities.** Certain communities have a greater unmet need for contraception, and these communities would greatly benefit from enhanced access to contraception. Poorer inner-city communities, remote rural (including indigenous) communities and communities within developing countries tend to have higher rates of unintended pregnancies and are more vulnerable to the adverse health, social and economic impacts associated with an inability to plan their family size.

● **Reducing adolescent pregnancies.** Rates of teenage pregnancy are particularly high in these vulnerable communities. Babies born to adolescents are at increased risk of low birth weight, infant mortality and poorer health and well being outcomes. Many adolescent girls who become pregnant leave school early, which can have long term implications for themselves, their family and their community.

● **Reducing infant mortality.** Family planning can prevent closely spaced and ill-timed pregnancies, which contribute to some of the world’s highest infant mortality rates.1

A reversible male contraceptive is an important new tool that can be used to tackle the unmet need for contraception around the world and to improve family planning. Importantly this contraceptive would enable millions of men to participate more fully in family planning.

A reversible male contraceptive: a new strategy to target a global unmet need for contraception

The World Health Organisation recognises that there is an unmet need for contraception in many parts of the world. Tackling this unmet need and offering improved methods of family planning is essential for improving the health and well being of both individuals and communities. Family planning allows people to have their desired number of children and determine the spacing of pregnancies; contraceptive use is an essential part of family planning.1
Alleviating the burden on women

- Women with an unmet need for contraception are defined by the World Health Organisation as those who are sexually active and are of reproductive age, are not using any method of contraception, and report not wanting any more children or wanting to delay the next child.
- Particular groups of women are more likely to have an unmet need for contraception, such as teenagers and women unable or unwilling to use (or perhaps intolerant of) conventional female contraceptives, in the post-partum period, as well as migrants, refugees and those living poorer inner city communities.
- Nearly 220 million women worldwide had an unmet need for contraception in 2015.
- More than two thirds of married women use female contraceptive methods.
- There are between 40-50 million abortions yearly worldwide equating to 125,000 per day.
- Nearly 800 million women who are married or in a relationship are projected to require access to contraception in 2030.
- A woman’s ability to choose if and when to become pregnant has a direct impact on her health and well being; improved access to contraception can prevent pregnancy-related health risks to women.

Providing a reversible contraceptive that can be used by the other half of the population will benefit millions of women worldwide.

Sources:

Fast facts on the market for a reversible male contraceptive

The Global Contraceptive Market has been predicted to grow from US$16 billion in 2013 to US$20 billion in 2020.

The only male contraceptive method included in this market estimate is condoms. If only a quarter of men who indicate their willingness to use a male contraceptive actually adopted the method, the potential market in only nine countries would be more than 40 million people.
Outcomes

This project will produce a long acting contraceptive implant for men. The contraceptive will be selected and shown to be well tolerated, desirable in its ease of use, effective and reversible.

Filling the gap between science and industry

Despite the fact that the pharmaceutical industry has withdrawn from the development of a new male contraceptive product, we know that there is a strong, worldwide need and market for a reversible male contraceptive. There is also recognition of an unmet need for a male contraceptive from large not-for-profit public sector agencies such as the World Health Organisation. This project will harness world-leading expertise and extensive prior experience and knowledge to develop the ideal product.

We will identify a new hormonal male contraceptive capitalising on decades of public sector research that will be attractive to a range of men in terms of its reliability, reversibility, safety and desirability. We will gather all of the essential pre-clinical and clinical information required before a product can be brought to market.
About Androfin
Board of Directors

Professor David Handelsman
MB BS (Melb) PhD (Syd) FRACP FAHMS

Professor Handelsman is a Professor of Reproductive Endocrinology and Andrology (1996), founding Director of the ANZAC Research Institute (1998) and founded Australia’s first Andrology Department at Concord Hospital (1999). With over 450 papers cited more than 20,000 times (h index 80), he is among the most highly cited authors worldwide on testosterone or androgens.

David is a career medical scientist and researcher in Andrology (male reproductive health, medicine and biology) with medical and specialist Endocrinology training and post-doctoral fellowships from NHMRC (UCLA) and Wellcome (Sydney) who rose to become Australia’s first Professor of Andrology in 1996.

He has been an international leader in the fields of androgen physiology, pharmacology and toxicology involving research in the basic, clinical, translational and public health areas. Most recently this has focused on genetic models of androgen action, steroid mass spectrometry, anti-doping science, and clinical and epidemiological androgen pharmacology.

His standing as an international authority on androgens is recognised by the award of the Royal Australian College of Physician’s Susman Prize (1994), AMA Men’s Health Award (2003), Lloyd Cox Memorial Lecture (2007), RFD Lecture (2010), Honorary Life Membership of the Endocrine Society of Australia (2008) and the Society for Reproductive Biology (2008) and election as a Fellow of the Australian Academy of Health and Medical Sciences (2015). In recent years he was invited to write editorials for the New England Journal of Medicine and Journal of the American Medical Association (JAMA) and his work was cited in a Time magazine cover story on testosterone. He has appeared as a Crown expert witness before Full Bench, Federal Court of Australia and as a medical/scientific expert on behalf of WADA and ASADA at anti-doping tribunals and the Court of Arbitration for Sports.

Over the last 3 decades he has been closely involved in all major international multi-centre male contraception clinical trials including designing, monitoring and drafting the manuscripts for the two landmark WHO male contraception studies. In Australia he directed many Australian path-finding studies and clinical trials for male contraception including designing and directing the original proof-of-principle study for a depot injectable male contraceptive, now the leading approach to hormonal male contraception.
Professor Robert Ian McLachlan
MB BS (Monash), PhD (Monash), FRACP AM

Professor McLachlan is a physician-scientist in male reproductive health with a program of translational research in sperm production, male infertility and contraception, assisted reproduction and reproductive endocrinology.

After specialty training in endocrinology, he obtained a PhD in Reproductive Medicine from Monash University in 1987 and then undertook a position as a Visiting Scientist at the University of Washington, Seattle, returning in 1990. He has since been continuously funded as a Research Fellow by the Australian NHMRC and has led the male reproductive research program at the Hudson Institute of Medical Research, Melbourne.

As Director of Clinical Research, he has established an internationally recognized research program in the endocrine and genetic regulation of spermatogenesis. He has made seminal contributions to understanding the hormonal regulation of sperm production in both animal and human models. In regard to human male hormonal contraception, his studies have included WHO-sponsored multicentre trials and, in conjunction with Prof David Handelsman, Concorde, Sydney, the world’s first efficacy study of a androgen–progestin combination (now the leading approach). He is also an expert in the diagnosis and management of male infertility, gonadotropin deficiency and the genetics of male infertility. In addition he has been Consultant Andrologist to the Monash IVF program since 1990, a Past President of the Fertility Society of Australia and a member of two WHO committees (Male Fertility Regulation committee and Expert Working group for the evaluation and management of male infertility).

Finally in the public domain, since 2006, he has been Director of Andrology Australia, a Federal Government funded initiative in research and community and professional education in male reproductive health - andrologyaustralia.org.

He has led efforts to improve clinical practice and health promotion, and has provided advice to government and industry. His work seeks to addresses gaps in male health and education, and to build the workforce by training clinicians committed to evidence-based practice.

He has published 249 original reports, reviews and chapters and has received awards; including the Eric Susman Prize (Royal Australasian College of Physicians) for research in internal medicine (2002), the 2014 Hoffenberg International Medal, of the British Society of Endocrinology, UK, and in 2016, he was made a Member (AM) in the General Division of the Order of Australia (2016) for his service to medicine in the field of endocrinology, particularly to men’s reproductive health, and to medical research.
About Androfin
Board of Directors (Cont.)

Peter Ritchie
B.Com, FCPA, AO

Peter Ritchie is the founder, Chief Executive and former Chairman of McDonald’s Australia having over 500 stores and 50,000 employees. Peter announced his retirement from an executive role at McDonald’s Australia after 25 years with the company and was non-executive Chairman until December 2001.

Peter has recently retired as Deputy Chairman of Seven Group Holdings Limited after 23 years with the group and is also a former Director of Westpac Banking Corporation. Peter has held numerous other Directorial and Chairman’s roles in both listed and unlisted entities worldwide, including on the Board of the McDonald’s Corporation in Oak Brook, Illinois, USA.

In 2003, Peter was honoured with an Order of Australia award for service to business, education and industry development in Australia by providing employment opportunities and training for young people, and to the community through corporate, financial and material support for health and educational facilities.

He holds a Bachelor of Commerce Degree and an Honorary Doctor of Business from the University of New South Wales.

Richard Bell  LLB

Richard is a businessman and philanthropist. In 1999 he founded 1800 Reverse, one of Australia’s most successful telecommunications companies, and as Chief Executive guided its international expansion into the UK, Ireland and New Zealand. He led its listing on the ASX achieving a market capitalization of +$500m before retiring from executive duties in 2007.

His investments include being the introducing shareholder partner in the fast-casual restaurant chain Guzman y Gomez, one of the fastest growing restaurant chains in Australasia, as well as having been exclusive importer of George Clooney’s’ Casamigos tequila.

Richard began his career as a solicitor in Brisbane before undertaking a number of roles in finance overseas, including in equities at S.G. Warburg and as Managing Director of Wilson HTM (USA), both in New York.

Tom Ray  B.Commun (Bus)

Tom is Chairman of the Perry Cross Spinal Research Foundation aiming to find a cure for paralysis. Since 2011 the Foundation has raised, from both private and government sources, significant funding toward olfactory stem cell research. Most notably the Foundation has funded the research of the 2017 Australian of the Year, Professor Alan Mackay-Sim.

He is a recently retired Councillor of Bond University where he served on the University’s Audit & Risk Management and Nominations Advisory Committees. In 2017 he was awarded Bond University’s Robert Stable Medal for exceptional achievement as a Bond Alumnus, the highest honour the Bond University Alumni Awards can bestow.

Tom is Executive Director of the Ray Group, a Queensland based property developer, which developed the $1 billion Salt Village integrated residential-resort precinct at Kingscliff in Northern New South Wales.

He began his career at John Singleton Advertising (Singleton Ogilvy & Mather) in Sydney becoming an Account Director before moving to Macquarie Bank Limited in 2000, joining the Banking and Property Group. Tom moved to London before returning to Australia in 2003 to take up a position with the Ray Group.
James C. Bell  
QC, BComm, LLB (Qld), LLM (Cambridge)  

James is a practicing Queen’s Counsel admitted to the Bar in 1976 and appointed Queen’s Counsel in 1993. He is an insurance and litigation specialist.

James has bachelor degrees in commerce and law from the University of Queensland, and a Master of Laws from Cambridge University. He is a certified mediator, having completed formal mediation training including the Mediation Programs at Bond University and the Harvard Law School.

He has a broad practice in advisory work, trials and appeals in both Commonwealth and State courts. Although most matters involve commercial disputes, he also has substantial experience in other areas, including regulatory matters concerning the legal profession and areas such as price setting for electricity supply. He has appeared in various Royal Commissions, including most recently as Counsel Assisting in the Queensland Racing Commission of Inquiry.

James is currently President of the Queensland Club.

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Jeff Frazer  
CA, CIA, RCA, B.Bus  

Jeff is a Partner at KPMG and has over twenty years experience in accounting, consulting and finance. His focus is on advisory and assurance service delivery, but with the nature of clients that Jeff works with, he has a broad range of skills including valuations, tax and accounting, financial reporting and transaction based engagements.

Jeff is a member of Chartered Accountants ANZ, a Registered Company Auditor, a Certified Internal Auditor with the Institute of Internal Auditors and has a Bachelor of Business degree. Prior to joining KPMG, Jeff worked in the financial markets on the Sydney Futures Exchange for Macquarie Bank Limited.

Jeff is extensively involved in advising Not-For-Profit organisations both in Queensland and nationally. He currently sits on the Board of Surfing Queensland and is the Company Secretary for LifeFlight Australia Ltd.
We believe that both men and women should be able to share the benefits and burdens of controlling their fertility and planning for a family. This contraceptive would be used by millions of men across many countries and would give them autonomy in their fertility control. By providing a truly effective and reversible contraceptive to men, we will be able to help avert millions of unwanted pregnancies and abortions worldwide.

We are seeking a total of $20 million dollars to fund the discovery of the ideal male contraceptive and to perform the clinical trials necessary to bring it to the market.

All funding will be used to fund the development of the world’s first reversible male contraceptive.

Contact Us

1300 263 763 (1300ANDROF)

For more information contact:

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Level 1, 30 Little Cribb Street, Milton QLD 4064

Or call us on
1300 263 763 (1300ANDROF)

Or email
admin@androfin.org