Tabled by LDAA,
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Lyme-like illness into the future

1. National Advertisement for Senate Inquiry Submission

AIM: To get greater reach of potential Lyme-like sufferers who do not use social media to make a submission to the Senate Inquiry on the growing incidence and issues surrounding Lyme-like illness in Australia

Do you know someone with a Lyme-like illness?

Stand Up, Be Counted: In November 2015 the Senate established an inquiry into Lyme-like illness in Australia. The purpose of the inquiry is to investigate incidence, diagnosis, treatment, research and discrimination associated with Lyme-like illness.

The Lyme Disease Association of Australia encourages patients, families, carers, treating practitioners, scientists and researchers to make sure the Senate hears of their experiences. It is important that everyone associated with Lyme-like illness makes a submission to help show how vast the problem is for Australians.

Submissions close 31 March 2016.

For further information, visit the Lyme Disease Association of Australia's Senate Inquiry page: http://www.lymedisease.org.au/senate-inquiry/

2. Lyme App

AIM: patient support opportunity. Develop an App to help patients practically manage their medication regimens, their appointments, symptoms. Could obtain a real-time database of symptoms and issues to populate a data repository for research. Could also use smartphone features to capture image database of rashes and visible signs and symptoms, field capture for images of ticks in situ (bites etc) and location services to spatially plot new tick bites, tick locations or other related situational data.

3. Patient support – professional advocacy arm

AIM: patient support opportunity. Many patients find themselves in situations where they are being involuntarily held or treated under duress, or insistence of their families. Others have no family and become dependent on the 'system' to advocate for them. An on call / distributed professional advocacy organisation/arm, trained in Lyme-like disease would be extremely beneficial for this patient cohort. The organisation could be further contracted to develop advocacy education information to support other professionals working in associated disability support organisations nationally.

4. Counselling, coaching and support services

AIM: patient support opportunity. Provide both a counselling and 24/7 on call telephone support service for patients. Many patients have mental health issues, many more are depressed. Patient support groups, while comforting for the majority, are neither qualified nor equipped to properly support people who are suicidal or are suffering with depression.

Coaching services like those in 'life-coaching' circles could be a helpful way to support patients who have trouble complying with their treatment regimens, or who have no family support; there are many. Advocacy support people and counsellors could work together in a case management arrangement to garner community services and other support the patient might be entitled to receive, or need.

5. Patient Assistance program

AIM: patient support opportunity. Many patients cannot afford treatment, or the basics of life. An assistance program to help patients obtain medication, treatment, diagnostic tests, consultation with doctors, they could not otherwise afford. The program could also offer support for travel assistance and accommodation for those who must travel long distances for treatment.

6. Legal support – discrimination

AIM: provide pro bono legal support for patients who suffer discrimination. Facilitate and advocate for non-discriminatory treatment.

7. Patient return to wellness programs

AIM: Role out support, coaching, rehabilitation, exercise programs, either self-directed or supported to help patients regain their health following Lyme-like illness.

8. Multidisciplinary treatment centres

AIM: patient support opportunity. Similar to treatment centres overseas, establish treatment centres where patients are offered holistic and multi-disciplinary team of medical professionals, including alternate therapists to heal mind, body and soul for patients.

9. Awareness and prevention campaign

Short term AIM: Infomercial style media, optimised for digital and highly compelling stories of the common symptoms of Lyme-like illness, with follow on message about prevention – best defence of Lyme-like illness is prevent a tick bite.

Concept 1: Similar to Under Our Skin trailer; opportunity to fast track UoS style piece by investigating royalty to use Australian footage from Emergence and using local media footage.

Concept 2: Assist Pooley family to produce their own documentary on their Lyme awareness journey around the country, or use their footage with permission. http://www.tickedoffandtravelling.com/

Longer term 2 AIM: Australian led documentary and investigative journalist piece on Lyme-like illness in Australia. Incorporating patient stories, Doctors, educational facts, numbers / prevalence and preventive message on end. Footage could be multi-purposed and repackaged for use in school education campaigns, occupational health training situations.

10. Tick Kits for Schools

AIM: prevention strategy targeted to children. Produce a *Tick Kit for schools* as a one off project to help raise awareness and prevent more tick borne disease in our most precious resource, our children. Anecdotal evidence suggests that schools are in a precarious position when it comes to their duty of care in preventing possible disease, especially for schools participating in excursions to tick infested areas. For schools in endemic tick areas, like coastal strips, we'd ideally like to see a prevention approach that is similar to that adopted in the SunSmart campaigns in relation to applying sunscreen, but using DEET based tick repellents instead.

Developed collateral and fully proposed package has already been drafted and costed (at approx. $330K). Needs to have a policy piece and significant liaison with state health departments to understand the regulatory environment for duty of care and processes in school environments.

11. Research

AIM: mulit-faceted research program:

Patient focused: with priority on studying patients/humans not ticks or potential causative agents. Investigation should include alternate forms of transmission through people processes: sexual, genetic, in-utero, blood transfusion (vertical and horizontal transmission) etc. Collection and collation of medical files of patients in participating Dr clinics could first provide the evidentiary data to design a broader program or systematic clinical study to gather empirical data on current patient situations vs control groups.

Clinical studies including incidence of Lyme cases using CSF samples already collected from menepidemiology on returnetravellers,

Alternate disease modelling:

Patient registers: systematic collection of empirical patient data on longitudinal study in partnership with medical professions to assist in documenting effective treatment processes for patients.

Disease correlation: spatial and temporal research on the incidence of Lyme-like illness modelled against patterns of disease with unexplained aetiology (cause), for example MS, EBV, Fibromyalgia, ME/CFS, Alzheimer's. There is too much data that correlates these illnesses for it to be co-incidental. Prioritise desk research of the tome of studies that already exist – look for gap and pursue.

Zoonotic : exploration of pathogens isolated in the Murdoch research, with further research funding to explore recent research. There are multiple papers concluding the discovery of a novel species that 'require further investigation' on the potential to cause human disease.

Review of the [Murdoch] companion animals / dogs as sentinels research to test the hypothesise, from as yet unwritten findings, on the 40% of dogs that cross reacted with the Snap40 test for *B.burgdorferi.* Hypothesis is that this could also be occurring for people.

Causative agent (host and environmental study): study on ticks and potential hosts we know that Murdoch finds a high incidence of relapsing fever from ticks (echidna specific ticks - Aponomma concolor) on echidna's. There is a hypothesis that Echidnas share similar environment as Bandicoot who are a well known host of Ixodes ticks.

Establish best practice pathology practices& tests: a desperate need for consensus on testing kits and associated risk factors. Explanation and understanding of discordant results. Investigation into and development of new and novel testing/ diagnostic tools. C6Peptide, masking techniques, next gen sequencing – what do they have to offer ? Use of SPECT in empirical evidence etc.

Consider competitive research sponsorship for PhD's.

Priority	Aetiology	Patients	Pathogen	Testing
1	Epidemiological study	Clinical study	*Borrelia* search	**Interim solution** for pathology testing & Treatment
2			Tick competence	Testing
3	Retrospective investigation	Treatment guidelines		

12. Support for Doctors

AIM: support for Doctors. Education – professionally accredited learning, training and case load reviews. Roundtable expert consultations [case reviews] established as diagnostic and learning opportunities. Doctor education kits and professional support for those needing advice on treatment, including early intervention treatment strategies, info on prophylactics etc. Sponsorship for ILADS training and assessment of potential to replicate ILADS training system in Australia.

13. International collaboration

AIM: explore opportunities to collaborate with groups internationally on same agenda. Caudwell Lyme Foundation, Lyme Education USA and other associations and organisations. Investigate opportunity to work with Mayo clinic and US Lyme disease treatment centres, BCA Germany and Klinik St.George and replicate dedicated treatment centres in Australia.

Connect international researchers, Brazil USA, Germany.

Patient focused Strategic Action Plan

1. Diagnosis and Testing

Major Issue: Patients experience difficulties obtaining a reliable diagnosis for Lyme-like illness in Australia.

Objective: *Ensure Australians experiencing Lyme-like illness can readily access affordable and reliable diagnosis and 'best practice' laboratory testing by 2016.*

Target for Change	Impediments		Strategies	Refer to:
Australian clinicians GPs & Specialists	Clinicians discount the possibility of Lyme disease in their diagnoses because an entrenched scientific position, based on a single study of indigenous ticks, leads them to conclude Lyme disease cannot exist in Australia, regardless of travel history and symptom presentation in their patients. They are also reluctant to consider diagnosing Lyme disease because of the controversy surrounding the disease.	1.1 1.2	CMO re-issue official statement regarding the existence of Lyme-like illness and the possibility of *Borrelia* or similar pathogen causing illness in Australia. Revise dissemination strategy to be more effective in reaching GPs.	
Australian clinicians GPs & Specialists	Clinicians frequently misdiagnose and recommend inappropriate treatment protocols.	1.3 1.4	Develop educational guidelines. Develop training program for clinicians in diagnosis of Lyme-like illness.	See Education Action Plan
ICPMR, PaLMS and referring laboratories	Australian laboratory tests appear biased towards a high false negative rate (when compared to same-sample overseas testing). Positive test results are often dismissed as being erroneous	1.5 1.6	Conduct a thorough review of current Australian testing procedures. Study laboratory practices in all countries testing for Lyme-like illness to ascertain 'best practice'.	See Diagnosis & Testing Action Plan
CMO CACLD	Uncertainty about the causative factors for Lyme-like illness in Australia has meant most clinicians rule out Lyme disease as a differential diagnosis.	1.7 1.8 1.9	Conduct epidemiological research based on current patients with Lyme-like illness. Conduct retrospective research. Conduct clinical research.	See Research Action Plan
CMO CACLD	Research into Lyme disease appears to falter once simplistic causative factors have been identified, leaving many questions unanswered as to alternate potential causes of Lyme-like illness, and patients can be excluded when their presentations of the condition fall outside narrow definitions endorsed for diagnosis and treatment.	1.10	Study the unique presentations of Lyme-like illness in Australia before conducting research based on assumptions from other locations where Lyme disease and Lyme-like illness occurs.	See Research Action Plan

2. Treatment

Major Issue: Australian patients with Lyme-like illness experience difficulties accessing appropriate and affordable medical treatment for their condition(s) and often encounter discrimination.

Objective: *Ensure all Australian patients with Lyme-like illness are able to access appropriate and affordable treatment by 2016.*

Target for Change	Impediments		Strategies	Refer to:
CMO/CACLD	Attention to developing treatment protocols for existing patients has been delayed due to scientific focus on identifying causative agents before acknowledging medical condition.	2.1 2.2 2.3 2.4 2.5	Consult with clinicians with most experience treating Lyme-like illness in Australia and overseas. Identify 'best practice'. Develop interim treatment guidelines endorsed by CMO. Ensure thorough dissemination of treatment protocols to all Australian clinicians. Develop training for clinicians.	See Treatment Action Plan for detail. See Education Action Plan for detail.
Australian clinicians GPs & specialists	Patients attending GPs & specialists are prescribed inappropriate treatments, particularly antidepressants and steroids.		See Strategy 1.1 See Strategy 2.3	See Treatment Action Plan for detail.
Public hospitals	Patients attending public hospitals (particularly emergency departments) have been refused treatment when revealing a Lyme diagnosis in their medical history.		See Strategy 1.1 See Strategy 2.3	See Education Action Plan for detail.
GPs & Public hospitals	Patients presenting with a recent tick bite have been refused early intervention treatment with antibiotics, or incorrect antibiotics.	2.6	Implement early intervention strategy where infection is suspected. Administer antibiotic treatment (6 weeks minimum).	See Treatment Action Plan for detail.
PBS	Patients treating Lyme disease bear unsustainable expenses because many of the prescribed medicines they require are not covered under Pharmaceutical Benefits Scheme (PBS).	2.7	Authorise inclusion of pharmaceuticals regularly used in Lyme treatment protocols on PBS.	See Treatment Action Plan
Medical community	There is an acute shortage of Lyme-aware doctors available to treat patients with Lyme-like illness in Australia.		Implement Strategy 1.1 to reduce controversy and stigma associated with Lyme-like illness. Implement Strategy 2.5 - training for clinicians.	See Treatment Action Plan

3. Public awareness/Risk protection

Major Issue: The Australian public has not been made aware of the potential risks of exposure to Lyme-like illness from ticks and other possible vectors nor has a national health policy been developed to address treatment issues.

Objective: *Reduce the risk of an epidemic of late stage Lyme-like illness by ensuring the Australian public is aware of the potential risks of exposure to possible transmission and by improving access to early intervention treatment protocols throughout Australia by 2016.*

Target for Change	**Impediments**		**Strategies**	**Refs/Timeframe**
DoH CDNA	There are currently no formal mechanisms in place to measure the incidence of Lyme disease or Lyme-like illness in Australia.	3.1 3.2	Monitor incidence of Lyme disease in the Australian population. Initiate a national surveillance program.	
The Australian Public	Australians are generally unaware of the potential sources of and risks associated with transmission of Lyme-like illness.	3.3 3.4	Develop and disseminate public awareness campaign. Erect warning signage in areas of potential high risk exposure.	See Education Action Plan for detail.
GPs & Public hospitals	There is no early intervention strategy in place for people being bitten by arthropods known to be potential vectors for Lyme-like illness.	3.5	Ensure all GPs are aware of risks and ready to administer appropriate treatment for early intervention.	See Treatment Action Plan for detail.
Red Cross & Organ Donation agencies	There is a risk of transmission through blood banks and organ donation, as opting out is voluntary and only an option for those who have been correctly diagnosed.	3.6 3.7	Screening of blood for *Borrelia*, *Babesia* and other known co-infections. Notification to organ donors to withdraw from program after suspected tick bites.	
GPs, public health facilities.	Mothers may be transmitting pathogens to babies during pregnancy and breast-feeding.	3.8	Issue public health warnings to prospective parents and treat expectant mothers to minimise transmission risk.	See Education Action Plan for detail.
Public Health Education Programs, Clinicians.	The general public is unaware of the possibility of sexual transmission of Lyme disease, particularly from partners who remain undiagnosed.	3.9 3.10	Issue public health warnings regarding potential risks of LD along with other safe sex warnings. Warn patients diagnosed with Lyme-like illness of potential risks to sexual partners.	See Education Action Plan for detail.

4. Social welfare & discrimination issues

MAJOR ISSUE: Patients with Lyme-like illness experience discrimination because their medical condition is not formally recognised.

Objective: *Ensure an end to discrimination by raising public awareness of Lyme-like illness by 2016.*

Target for Change	Impediments		Strategies	Refs/Timeframe
Australian clinicians GPs, Specialists & Public Hospitals	Patients attending GPs, specialists and public hospitals (particularly emergency departments) have been subjected to humiliation and refused treatment when revealing a Lyme diagnosis in their medical history.		See Strategy 1.1.	See Education Action Plan for detail.
Department of Human Services / Centrelink	Patients have been denied welfare income payments, as Lyme-like illness is not recognised as an official medical condition. Children are denied disability supports because their illness is not currently listed for consideration on Centrelink paperwork.	4.1	Raise awareness of Lyme-like illness in public institutions including the relapsing recurring nature of manifestations	See Education Action Plan for detail.
GP, Public hospitals, DCD, Child welfare agencies	Parents have been threatened with losing custody of their children due to school non-attendance and/or told their children's obvious symptoms are psychosomatic when revealing they are suffering from Lyme-like illness, or are accused of Munchausen's syndrome by proxy.		As per 4.1	See Education Action Plan for detail.
Schools	Children suffering from Lyme-like illness are unable to perform to their potential and are frequently unable to attend school.	4.2 4.3	Open up pathways for partial homeschooling options. Provide additional in-school support options.	See Education Action Plan for detail.
Workers' comp & Insurance companies	Workers' compensation and income protection insurance claims are frequently rejected due to official ambiguity over existence of Lyme disease in Australia.	 4.4	See Strategy 1.1. Improve diagnosis and testing.	See Education Action Plan for detail.
CMO/Medicare	Disparity of costs between patients in tests available to them for diagnosing and testing Lyme disease.	4.5	Implement diagnostic guidelines	See Diagnosis & Testing Actions Plan
Australian public	Patients suffer from social discrimination due to the invisible, and sometimes alarmingly visible, symptoms of their disability.		See Strategy 1.1.	See Education Action Plan for detail.

5. Education Action Plan – in further detail

Target audiences	Tasks
All Australians	CMO to make a formal announcement to the Australian public regarding the existence of Lyme-like illness among Australian patients and the need to take precautions while research into potential transmission sources are further researched.
All Australian clinicians	Develop and disseminate educational packages on the background, diagnosis and treatment of Lyme-like illness. (Refer to 7. Treatment Action Plan for further details.)
Radiologists, IDS, Neurologists, private and public practices of specialists	Develop and disseminate specialist diagnostic and treatment guidelines for clinicians involved in differential diagnosis.
Government agencies, Educational institutions, public health centres, Centrelink, DCS	Develop and disseminate education packages providing medical background, care considerations and risk protection information regarding Lyme-like illness.
General public Private health centres, National Parks, State forests, coastal recreation areas, public and private camping areas, school camps	Develop public risk awareness campaign identifying arthropods suspected as sources of infection. Including: print and electronic media packages; signage in public areas; advertising and media stories.
Occupations with high risk of vector exposure Farming, bush regeneration, land care, forestry, mining, outdoor recreation and tourism industries	Develop risk awareness information for inclusion in industry WHS guidelines. Prepare news articles for distribution in industry newsletters. Best practice example: http://www.aabr.org.au/aabrs-tick-guide-now-available/
Public, including prospective parents via GPs & Public Hospitals, sex education programs.	Develop awareness information brochures to advise of 'potential risk' via sexual and in utero transmission.

6. Diagnosis and Testing Action Plan – in further detail

Timeframe	Tasks
Immediate	CMO to establish Review committees/working groups for Diagnosis and Testing.
Interim step	Develop interim diagnostic guidelines in consultation with Australian doctors treating Lyme-like illness and based on local disease presentations.
By 2015	Research Brazil's diagnostic tools for BYS in the development of a diagnostic pathway.
By 2016	Common differential diagnosis symptoms should be developed for Australia once clinical studies have determined the most common aspects of Australian Lyme disease or Lyme-like illness.
By 2016	Develop guidelines for diagnosis of the most common Australian co-infections.
Medium	Full review of all Australian laboratories conducting Lyme disease testing to determine test method used, genospecies tested, actual testing practices compared to test kit guidelines.
By 2015	Study laboratory practices of all countries testing for Lyme-like illness to ascertain 'best practice'.
By 2015	Establish criteria for eligibility and standardise testing process for all Australian laboratories involved in testing for Lyme disease.
By 2015	Reference labs to be established based on a statement of requirement.
By 2015	Only reference labs testing for *B. burgdorferi, garinii and afzelii* will perform two-tier testing (ELISA and immunoblot).
Interim step	Local pathology laboratories cease performing screening ELISA tests until standardised testing processes are established..
Immediate	Testing process to outline steps to ensure samples are analysed within 3 days of collection.
Immediate	Changeover of ICPMR Lyme disease testing to European ELISA and immunoblot test kits.
Interim step	All Lyme disease testing to be performed by Australian Biologics or PaLMS until ICPMR has updated and verified their new testing procedures. Standardisation of criteria used to determine positivity on Western Blots.
Immediate	Patients and clinicians to be provided with details of which laboratory has performed their testing and the full results (showing species tested and bands detected).
Immediate	CMO to provide national clinician advice to reflect the testing process (revise the NSW Government version).
By 2015	Analyse historic immunoblot results to determine characteristic bands in patients with Lyme-like illness acquired in Australia and use to refine immunoblot interpretation guidelines.
By 2016	Testing capability to be developed for potential co-infections.
By 2015	Conduct studies into other diagnostic tools, including, but not limited to: • microscopy tests for detection of spirochaetes • latest culture methods • nested PCR in conjunction with DNA sequencing tools • lymphocyte transformation test (LTT) • SPECT scans
By 2015	Review /recall Westmead tests results in which 'false positive' result was given on basis of 5-bands requirement. Request these patients retest once processes are revised and refined.

7. Treatment Action Plan – in further detail

Timeframe	Tasks
Immediate	Formally authorise doctors to treat Lyme disease or patients with Lyme-like illness, irrespective of where they are diagnosed, without repercussions.
By 2015	Develop interim guidelines, potentially based upon European guidelines, and disseminate to all hospitals, general practitioners and infectious disease doctors in Australia.
Immediate	Consult current treating practitioners in the development of any Australian treatment guidelines, either interim or final.
By 2015	Develop a standardised Australian 'criteria' for diagnosis to underpin the development of a diagnostic pathway.
By 2015	Develop educational material for doctors containing information on: • importance of differential diagnosis of Lyme disease and clear articulation of early, late and chronic stages of Lyme requiring different treatment strategies; • the Jarisch-Herxheimer reaction following administration of antibacterials; • chronic and relapsing nature of illness, also L-forms, cyst forms, cell wall deficient biofilms and the possibility of co-infections; • treatment of co-infections, where a 'layered' approach to treatment may be required, and non-bacterial co-infections (Babesiosis) require alternate treatment protocols; • the inappropriate prescription of steroids and /or anti-depressants (especially if the case is differential); and, • early intervention treatment strategies following a tick bite.
By 2015	Develop appropriate specification of the medications required to treat Lyme disease on medical schedules and the PBS.
By 2016	Conduct epidemiological studies (Rec 7) and clinical research into the unique Australian presentations of the illness (Rec 4) before developing final treatment guidelines in Australia.
By 2015	Review the range of complementary therapies currently being used in the treatment of Lyme-like illness to evaluate which may be efficacious and worthy of inclusion in recommended treatment protocols. For example, diet, detoxification, herbal, vitamin or mineral supplementation protocols.

7. Research Action Plan – in further detail

Patient community's priorities for research projects proposed in response to the Scoping Study.

Priority	Etiology	Patients	Pathogen	Testing
1	Epidemiological study (Rec 6)	Clinical study (Rec 4)	*Borrelia* search (Rec 1)	**Interim solution** for pathology testing & Treatment
2			Tick competence (Rec 2)	Testing (Rec 3)
3	Retrospective investigation (Rec 5)	Treatment guidelines (Rec 7)		

The LDAA agrees in principle to the research projects proposed in the Study and proposed two additional research proposals (at Rec 6 & 7). What follows is a summary of the noted considerations the LDAA would like to see implemented in research projects on behalf of patients:

Study 1: Experimental program to determine whether there is a Borrelia species in ticks in Australia causing Lyme-like disease, or whether another tick-borne pathogen is involved in human Lyme-like disease.	
1.	Samples should be collected from coastal, mountain and desert terrains and from areas where people are reported to have a Lyme-like illness.
2.	Collections and studies should not be limited to ticks; samples of all biting insects, fleas, mites, keds (biting flies), lice etc. should be considered.
3.	Other potential pathogens should be included in this study; *Babesia, Bartonella, Anaplasma, Ehrlichia, Rickettsia* and other pathogens and viruses should be included in the study along with *Borrelia*.
4.	*B. Queenslandica* should be acknowledged as a potential strain.

Study 2: Are Australian ticks competent to maintain and transmit B. burgdorferi s.l. genospecies or other Borrelia species associated with relapsing fever?	
1.	Vector competence studies should not be limited to ticks; where spirochaetal matter is discovered in other insects, their vector competence should be properly investigated.
2.	Evidence already exists to indicate that Australians are infected with more than one strain of *Borrelia*; research should investigate the multiple strains present within the samples collected and provide transparent calculations of the competence of those vectors to transmit multiple organisms, not simply *Borrelia.* Rates of transmission also necessitate investigation.
3.	Research on strains known to cause relapsing fever should be correlated with clinical evidence of patients who are presenting with relapsing fever syndromes.
4.	Native fauna should be considered in the examination of potential reservoirs and should be included to determine whether there is a native Lyme-like organism; it is important to understand the epidemiology, as there may be more than one vector involved. The Study should include identification of native Reservoirs for Lyme and Lyme-like disease and associated co-infections.

Study 3: Do we have the best reagents for detecting novel Borrelia species, including B. miyamotoi, especially in clinical specimens?	
1.	Interim testing arrangements and standardisation of testing protocols are urgently required.
2.	Some Australian private laboratories are already using sophisticated PCR techniques and isolating *Borrelia* and spirochaetal organisms. Every effort should be made to include any research evidence to continually improve the diagnostic and confirmatory testing protocols.
3.	The DoH should immediately conduct a formal review into the current test process in use at the public health laboratories, specifically in light of the sub-optimal testing materials currently in use at Westmead.
4.	The DoH should immediately, and formally, liaise with overseas testing laboratories that are providing positive tests to Australian patients to gain an understanding of their test processes, antigens used, primers and sequences.

Study 4: Clinical studies of patients presenting with symptoms suggestive of Lyme or Lyme-like disease.	
1.	Prospective clinical studies of patients must include an inquiry on alternate forms of transmission, for example, from an infected person to a sexual partner, or to a foetus, or via breastfeeding, as well as blood-to-blood contact or via transfusion.
2.	A program of research needs to commence immediately to gather and collate symptom information from Australian treating doctors to underpin a detailed map of the constellation of symptoms unique to Australian patients.
3.	Samples from patients not presenting with an EM rash should not be excluded from investigation.
4.	The DoH should work collaboratively with the patient groups to assist with the longitudinal survey of patients conducted annually.
5.	Any clinical study must investigate the manifestations of disease, especially in regard to early and late stages and 'chronic Lyme'.
6.	The Indigenous population should be studied to ascertain whether there is a history of Lyme-like illness in Australia or possibility for immunity to develop.
7.	All clinical studies must abide by the strictest ethical principles, be conducted in an open and transparent manner, with full declaration of any conflicts of interest.
8.	All clinical studies must recognise the specific impacts that studies will have upon children, who are most at risk.

Study 5: Retrospective investigation of chronic cases of Lyme borreliosis	
1.	Testing processes and considerations outlined in research project 3 must be a precursor to qualifying patients.
2.	Testing should not be limited to serological tests (ELISA and IFA), as many studies have shown negative serology in chronic cases with other indications of active infection, such as PCR positive and Elispot positive results.
3.	Evaluate the efficacy of SPECT scans in the diagnostic process.
4.	Samples used to qualify patients for any prospective studies must meet an agreed criterion and be conducted with the latest scientific knowledge and best laboratory technology available.
5.	Research should include patients from every demographic group who can share their stories, their medical results and their histories as part of a formal retrospective study as well as currently treating doctors who are prepared share their records.
6.	Any review of consolidated patient data, should not be limited to infectious diseases experts only and should include other independent experts.
7.	A panel of "experts" should include at least two physicians with extensive experience in diagnosing and treating chronic Lyme disease in Australia.
8.	All clinical studies and retrospective investigations conducted should be carried out with proper ethical approaches where full disclosure of any prior involvement in Lyme disease or Lyme-like illness is made transparent.

Study 6: Epidemiological research	
1.	As a matter of urgency, the LDAA recommends a *full* epidemiological study that also includes, but is not limited to, the addition of the following:
a)	A baseline quantification of Australians with diagnosed Lyme disease or Lyme like illness, to satisfy the Terms of Reference of the Clinical Advisory Committee on Lyme Disease (CACLD). Data collected should include demographics such as prior travel history, geographical location, bite history, disease duration etc.
b)	Monitoring of Lyme and Lyme-like cases by the CDNA in light of the emerging incidence of Lyme-like illness occurring in Australians who have never left the country (LDAA 2012). A transparent and open disclosure of the criteria and processes used for monitoring and surveillance of Lyme disease or Lyme-like illness in Australia is required.

Study 7: Development of a treatment options pathway - is included in the Treatment Action Plan of this section.

LDAA Mission

The aim of the LDAA is to:

- Educate the public and medical sector about the risks of Lyme disease and the need for early diagnosis and treatment (early detection makes this an easily treatable disease).
- Raise awareness of Lyme disease and other tick-borne Illness in Australia.
- Fundraise to support education of doctors and other health professionals about treating Lyme disease and ongoing patient care through antibiotics, diet and lifestyle changes and integrative therapies.
- Facilitate better testing and treatment.
- Distribute education materials to doctors and other health professionals about Lyme disease in Australia.
- Use the media to alert the public about Lyme disease in Australia.
- Support research into Lyme disease in Australia and learn from international experience.
- Collate personal stories which will bring pressure to bear on the Health Department who currently claim there is no Lyme disease in Australia.
- Highlight the probability that Lyme disease may be the actual cause of many serious health problems including, Parkinson 's disease, ALS, (Lou Gehrig's Disease), Motor Neurone Disease, Multiple Sclerosis, Fibromyalgia and M.E./Chronic fatigue Syndrome.
- Invite professional people to support us and join this association.
- Promote tick safety measures to the public for avoiding contracting Lyme disease and co-infections.
- Fundraising activities to support: education of doctors; facilitate initial testing of individuals querying Lyme; research through Karl McManus Foundation and others; legal defence and activism.